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_____ Monica Morrow, M.D.

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13. ABSTRACT *(Maximum 200*

The purpose of the component studies in this grant is to increase the utilization of available interventions for the screening, diagnosis, and treatment of breast cancer, particularly by the medically underserved. Risk factor information has been obtained for 7498 healthy women. To date, 991 non-English-speaking women have had breast cancer teaching through a peer health educator, and 48% have gone on to have mammograms. 99 nurses from city/minority health clinics have undergone a 16-hour educational intervention, with post-test scoring improving in 81and 84% improving breast exam skills on a standardized patient. A randomized trial of the effect of same-day mammography on patient compliance, utilizing different practice settings, has enrolled 166 of 200 women in a public health clinic and completed enrollment of 120 from an internal medicine private practice, and 177 Hispanic women have been randomized to a dietary intervention study. Interactive video conferencing is successfully occurring at off-site hospitals. Data has been collected on 1121 core biopsies and 501 surgical biopsies for a study of cost-effectiveness of core biopsy, and 41 patients entered into a randomized trial of cost effectiveness of inpatient vs outpatient bone marrow transplantation.

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Monica Morrow MD 8/13/99

PI - Signature Date

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OVERVIEW OF PROJECTS

The goal of our grant "Increasing Access to Modern Multidisciplinary Cancer Care" is to increase the utilization of currently available screening techniques and breast cancer treatments, particularly in medically underserved populations. This goal is addressed in the eight component projects of the grant, which are grouped under the general themes of a core facility upgrade, education initiatives for health care providers and patients, direct interventions to increase the utilization of proven treatments, and evaluations of the cost-effectiveness of new technologies.

The component projects of the grant, the principal investigators, and the specific aims of each project are described below.

Core Facilities Upgrade

Project #1: Epidemiology Database
PI: Monica Morrow MD

The specific aims of this project are to identify and collect risk information on a group of 10,000 women without breast cancer during the period of the grant. In addition, the existing breast cancer database will be expanded to include a few additional risk factor data points.

Education Initiatives for Providers and Patients

Project #2: Chicago Ethnic Community Breast Cancer Education and Screening: Woman to Woman Outreach
PI: Miriam Rodin MD PhD

The objective of this project is to develop training programs in breast cancer screening modalities for health advocates and peer health educators for dissemination along peer health information pathways. This program will target linguistically isolated minorities.

Project #3: Breast Education for Minority Providers
PI: Monica Morrow MD

The specific aims of this study are to develop a breast health curriculum for nurses which includes identification of risk factors, knowledge of normal anatomy and physiology, current techniques of breast cancer screening, diagnosis, and treatment, and community resources for the support of breast cancer patients. This project will educate minority care providers in breast health as defined by the curriculum, as well as in the techniques of clinical breast exam and breast self-examination instruction.

Direct Interventions to Increase Utilization of Services and Clinical Trials

Project #4: Increasing Adherence to Screening Mammography Recommendations
PI: Nancy Dolan MD

The objective of this project is to determine whether the combined use of targeted messages and same-day mammography increases adherence among women who receive physician screening mammography recommendations. This will be studied in an academic general medicine practice, a private practice, a geriatric practice, and a public health clinic.

Project #5: Breast Cancer Risk Reduction in Hispanic Women
PI: Marian Fitzgibbon PhD

The specific aims of this study are to conduct a prospective, randomized trial of an 8-month dietary intervention that is low in fat and high in fruits and vegetables in premenopausal Hispanic women. The frequency of breast self-examination and anxiety related to breast self-examination will also be

measured. Serum carotenoids and total fatty acids will be used as intermediate biomarkers for the dietary intervention.

Project #6: Multidisciplinary Networked Breast Cancer Conference
PI: William Gradishar MD

The specific aim of this project is to make available the expertise of an academic multidisciplinary breast cancer management team to practitioners in hospitals in the Northwestern Healthcare Network in order to optimize selection of local therapy, the use of adjuvant systemic therapy, and patient participation in clinical trials.

Cost-effectiveness of New Techniques

Project #7: Cost-effectiveness of stereotactic biopsy versus excisional biopsy for women with abnormal mammograms
PI: Charles Bennett MD PhD

The goal of this project is to develop a model which will accurately generate cost-effectiveness estimates for stereotactic breast biopsy versus excisional biopsy. This model will be tested using mammographic lesions of varying degrees of suspicion and different modalities of local therapy. Costs will be determined to the completion of local therapy rather than to the diagnosis of carcinoma.

Project #8: Inpatient versus Outpatient High-dose Therapy
PI: Jane Winter MD

The specific aims of this project are to compare the costs of inpatient versus outpatient high-dose therapy and autologous stem cell reinfusion, and to measure quality of life for patients during each of these interventions. The cost analysis will include not only hospital and physician costs, but out-of-pocket costs to patients and caregivers in the outpatient intervention.

Project 1: Epidemiology Data Base

PI: Monica Morrow, M.D.

Introduction

The identification of women at increased risk for the development of breast cancer is an important goal for screening programs and the prevention initiatives. Although multiple risk factors have been identified, the interaction between risk factors is poorly understood. In addition, information on risk has been derived for the entire population of women with invasive breast cancer. It is not clear whether all types of invasive carcinoma share common risk factors. The increasingly frequent identification of women at risk due to precursor histologies such as ductal carcinoma in situ, lobular carcinoma in situ, and atypical hyperplasia has raised important questions about interactions between these variable and other know breast cancer risk factors. The concordance, or lack thereof, of risk factors between women with invasive carcinoma and those with high-risk histology also has the potential to offer important clues as to the natural history of these precursor lesions.

A detailed breast cancer database is in place at the Lynn Sage Comprehensive Breast Center which includes information on risk factors, method of diagnosis, local and systemic therapy, and outcomes for cancer patients treated at the Center. A total of 1342 patients have been entered in this database since its inception in July 1995. The purpose of this project is to collect risk data on a cohort of 10,000 women without breast cancer for use as a control population in comparative studies of risk factors.

WORK TO DATE

A. Accrual of research subjects

Our target for patient accrual was 2000 patients in year 1, and 3000 patients in years 2 and 3. At present, 7498 questionnaires have been completed. By completion of the fiscal year, we will be at or extremely close to our stated goal of 8000 subjects by the end of project year 3. Data on 6698 of the subjects has been entered into the database and is available for exploratory data analysis.

B. Exploratory Data Analysis

Data analysis was projected to begin in year 3. At this time 6504 risk profiles are available for analysis. This figure excludes the 33 women diagnosed with breast cancer after completion of the questionnaire. Data on demographic factors and distribution of risk factors for this group of women is shown on the next 4 pages. Fields listed as "unknown" are those which participants declined to answer.

C. Key Research Accomplishments

Accumulation of a large cohort of women with detailed risk factor data continues on schedule.

D. Reportable outcomes – None to date

E. Conclusions

At the conclusion of year 3 of this project we have fulfilled our major objective in the statement of work by collected risk factor data on almost 8000 women and beginning

exploratory data analysis. In project year 4 we will complete patient accrual, continue data analysis, and develop a plan for long-term follow up of this cohort.

Demographics of Cohort
N= 6504

Mean Age: 51.93 (19-93)

Race		
Asian	193	(2.97%)
Black	879	(13.51%)
Declined	3	(.05%)
Hispanic	191	(2.93%)
White	5148	(79.15%)
Other	43	(.66%)
Unknown	47	(.72%)

Education		
< HS	88	(1.35%)
HS	1275	(19.60%)
College	2970	(45.66%)
Graduate	2126	(32.69%)
Unknown	45	(0.69%)

Insurance		
HMO	1141	(17.54%)
Medicaid	77	(1.18%)
Medicare	204	(3.14%)
Medicaid+	721	(11.09%)
PPO	3054	(46.96%)
Private	1044	(16.05%)
None	50	(.77%)
Unknown	213	(3.27%)

Income		
< 10,000	962	(14.79%)
10-30,000	2608	(40.10%)
> 30,000	1604	(24.66%)
Declined	259	(3.98%)
Unknown	1071	(16.47%)

Occupation		
Homemaker	902	(13.87%)
Managerial	3263	(50.17%)
Operators	61	(.94%)
Service	674	(10.36%)
Technical	861	(13.24%)
Other	615	(9.46%)
Unknown	128	(1.97%)

Mean Age Menarche: 12.67 (7-20) *database does not accept values outside this range
Mean Age Menopause 46.11 (15-65)

Menopausal Status		
Menopausal	3400	(52.28%)
Premenopausal	3048	(46.86%)
Unknown	56	(.86%)

Cause of Menopause		
Surgery	1224	(36.00%)
Natural	1838	(54.06%)
Unknown	338	(9.94%)

Pt with hx of ovarian cancer 13

Distribution of Risk Factors
N =6504

Pregnancies

Nulliparous	1909	(29.35%)	Average # Pregnancies	2.74 (1-19)
$P_{>0}$	4550	(69.96%)	Average # Live Births	2.36 (1-12)
Unknown	45	(.69%)		

Average age at first live birth 25.91 (13-49)
Average age at last live birth 30.46 (14-47)*

Prior Biopsy

True	1077	(16.56%)
False	5315	(81.72%)
Unknown	112	(1.72%)

Average # prior bx: 1.38 Missing

Prior Bx Results

Atypical Hyperplasia	35	(3.25%)
Lobular Neoplasia	0	
LCIS	6	(.56%)
Unknown/benign	862	(80.04%)
Missing	174	(16.16%)

Current Hormone Use

Estrogen replacement

True	2085	(32.06%)
False	4401	(67.67%)
Unknown	18	(.27%)

Mean Duration (months) 86.74 (1-710)

Oral Contraceptives

True	563	(8.66%)
False	5917	(90.97%)
Unknown	24	(.37%)

Mean Duration (months) 127.55 (1-410)

Other Hormones

DHEA	2	Megace	6
Evista	7	Testosterone	2
Lupron	3	Unspecified	6

Diabetes

True	257	(3.95%)	Average age at dx 44.45 (1-88)
False	6087	(93.59%)	
Unknown	160	(2.46%)	

BSE

>1/month	582	(8.95%)	Ave # Times per Month: 3.95 (2-30)
1/month	2082	(32.01%)	
Altmonth	1163	(17.88%)	
Rarely	2193	(33.72%)	
Never	408	(6.27%)	
Unknown	76	(1.17%)	

Average Weight (lbs)	150.9 (78-367)
Average Height (in)	64.67 (39-91)

Alcohol

Regular Consumer

True	4735	(72.80%)
False	1747	(26.86%)
Unknown	22	(.34%)

Average Alcohol Consumption in Past Year						
	Beer	%	Wine	%	Liquor	%
<1 drink per month	4383	67.39	2553	39.25	4548	69.93
1-3 per month	860	13.22	1322	20.33	800	12.3
1 per week	296	4.55	502	7.72	271	4.17
2-4 per week	333	5.12	944	14.51	286	4.40
5-6 per week	76	1.17	327	5.03	75	1.15
1 per day	53	.81	291	4.47	96	1.48
2-3 per day	30	.46	214	3.29	49	.75
4-5 per day	3	.05	11	.17		
>6 per day	1	.01			1	.01
Unknown	469	7.21	340	5.22	378	5.81

Cigarettes

Smoked >100 cigarettes in lifetime

True	3133	(48.17%)
False	3352	(51.54%)
Unknown	19	(.29%)

Ave age started smoking	19.07 (7-78)
Ave # cigarettes per day	15.86 (1-100)

Current smoker

True	751	(11.55%)
False	5659	(87.01%)
Unknown	94	(1.44%)

Current ave # cigarettes/day	12.64 (1-42)

Family Medical History

Diabetes n = 2081		
One 1st degree relative	961	46.18%
One 2nd degree relative	477	22.92%
Two 1st degree relatives	157	7.54%
One 1st and one 2nd	155	7.45%
Other*	331	15.91%

Ovarian Cancer n = 377		
One 1st degree relative	185	49.07%
One 2nd degree relative	125	33.16%
One 3rd degree relative	41	10.86%
Other	26	6.90%

Breast Cancer n = 1855		
One 1st degree relative	670	36.12%
One 2nd degree relative	645	34.78%
One 1st and one 2nd	161	8.68%
One 3rd degree relative	95	5.12%
Other	284	15.30%

Project #2: Chicago Ethnic Communities Breast Cancer Education and Screening Woman-to-Woman Outreach.

P.I.: Miriam B. Rodin, MD, PhD

1. Purpose

The purpose of this study is to field test a model of peer education to increase breast cancer awareness and knowledge and to facilitate screening adherence among non-Hispanic immigrant and minority women in Chicago. The peer educator model has attracted the interest of public health agencies as a way to extend health personnel and to achieve language and cultural competence in outreach to under-served communities. Scientific evaluation of this model of health education is sparse, although recent studies support the effectiveness of such interventions in African-American communities. [1,2] It is not known how generalizable these results are in culturally diverse communities. A secondary goal of this project is to examine qualitatively factors which support or do not support the peer educator model in specific culturally defined groups. In order to do so, we have contracted with seven community-based organizations (CBO's) serving distinct language and cultural communities to supervise, recruit and assist in training lay women to serve as peer breast cancer educators. The specific aims are (1) to determine whether peer education results in increased adherence to mammography screening guidelines and to practice of breast self-exam (2) to determine whether early detection adherence is associated with measures of attitude (decisional balance), belief (self-efficacy, fear) and knowledge (3) to discover community and cultural patterns related to measures of attitude and belief about breast screening and (4) to evaluate the effectiveness, regardless of the mechanism, of peer education in diverse communities.

2. Scope

The project supports seven sub-contracted agencies for the recruitment, training and supervision of peer educators (PE). A standardized curriculum is delivered to volunteer women generally at the offices of the sponsoring CBO. All prospective peer educators complete a standard set of translated pre- and post-test questionnaires (see below). To date, we have worked with 9 agencies: ECAC (Ethiopian Community Association of Chicago for Amharic, Eritrean, Somali, Tigrean); AHS (Asian Human Services for Indian subcontinent Hindi, Urdu and Gujarati languages, and recently Vietnamese); CASL (Chinese American Service League for Mandarin and Cantonese) and AIHS (American Indian Health Service). Korean women were reached first through the Korean American Community Health Clinic, now part of the Chicago Department of Public Health. Currently we have subcontracted to Korean American Community Services, a provider of aging-related services. We have recently subcontracted with Arab American Action Network as a replacement site for Filipino American Community Services There have been personnel changes within subcontractor agencies necessitating training of new health advocates. We continue to provide training in the program curriculum: orientation to women's health, breast cancer facts, breast self-exam and techniques for outreach. As new personnel are trained, pre-test and post-test protocols are implemented. Regular sessions for testing community women are held at community sites during which the questionnaire forms are administered and BSE technique is observed and scored. Since the last report we have undertaken additional instrument refinement. The instruments were item-analyzed order to select the subset of items which most reliably measured the constructs. Given low literacy and time constraints of childcare and work, it is desirable to work with shorter instruments. Results are presented below.

3. Work to date

With replacements described above, we are at capacity with 7 subcontracted CBO's, each with a 0.25 FTE staff position for a community health advocate (HA) charged with recruitment, assisting in training and supervision of up to 6 peer educators. Seventeen PE are currently active from last year's cohort, 5 more are in training. In addition, the health advocates assist interested women to obtain and follow up screening mammograms. To do so, the HA have developed working relationships with City of Chicago Department of Public Health (CDPH) screening sites and the mobile mammogram van, Cook County Hospital Breast Clinic and private providers. They schedule mobile van visits, arrange for group and individual appointments at which they also provide interpreter services. Common problems in system access are discussed in monthly staff meetings with sharing of resources and strategies. One recent example is appended.

4. Interim findings

To date, 991 women have had at least one documented teaching contact. This total does not include Southeast Asian women enrolled in a concurrent related study, nor does it include women who attended formal and informal peer teaching sessions who declined to fill out initial contact sheets. Of the 991, 476 (48%) had a mammogram as a result of this project. We are aware of 9 abnormal mammograms resulting in 4 biopsy-confirmed malignancies. Informed consent and research post-tests have been completed by 207 PE and PE candidates and by 267 community women. This rate of participation is close to our initial estimate

At baseline participating women ranged in age from 16 to 87 with a median of 52 years. In education, they ranged from 0 to post-graduate with a median of 9.5 years,

however 33% had 6 or fewer years of formal schooling. Fifty percent of the women had three or more children at home for whom they were responsible. Employment outside the home was reported by 41% of the women. English fluency was reported as "very little" to "none" by 44.6% of the women, 29.1% reported fluency in English. However 101 of the 188 "fluent" women were Native American. Similarly 42.9% of the women reported that they could not read English; 34.6% could read English well, but again most of these were Native American. Medical care is covered by private insurance for 19.6% of women; 15.5% reported they had Medicare; 26.6% reported Medicaid coverage. The remaining 38% had no third party coverage. About 30% of women had no usual source of medical care. Fifty-one percent of women reported that they had had at least one mammogram. Fifty-three percent of women who had had a mammogram had done so within the project period of 1996-99. Thus only about 25% of women were nearly adherent to screening guidelines. Sixty-two percent of women reported that they examine their breasts; however 68% of self-examining women also said that they did so only "sometimes," i.e., less than once a month.

As stated previously, the original questionnaires for pre- and post-testing consisted of a demographic form from which pertinent items are reported above. Also included in the packet were a five level Stages of Adoption scale adapted from Rakowski et al., [3] a 12-item decisional balance for mammography adapted from Velicer et al., [4] an abbreviated 15-item Health Beliefs questionnaire adapted from the 39-item Champion scale [5] and a 15-item (10 true-false, 5 multiple choice) Breast Facts Questionnaire (BFQ). Preliminary analyses indicated that this form was not performing acceptably and a revised form was developed as reported below.

In the first phase of the research, the full 39-item HBQ was employed, but the literacy levels of the research participants rendered this burdensome. Successive item analysis permitted the 39-item scale to be shortened to 15 items. A factor analysis of the 15 five-point Likert-scale belief ratings in the HBQ suggested that eight items in two subscales captured the variance in responses. The "Fear" scale is the sum of 4 ratings of beliefs about susceptibility to breast cancer and the seriousness of breast cancer (items # 4,7,9,18). The "Self-efficacy" scale includes 4 ratings of beliefs about the effectiveness of self-initiated measures and medical treatments (items #20,22,23,33). Based on pre-test data, the test-retest correlation for Fear was estimated at 0.68. For the Self-efficacy scale the test-retest correlation was estimated at 0.18.

The MDB questionnaire included 12 mammogram beliefs, six positive and six negative, rated on 5-point Likert scales. Item-analysis permitted us to retain six items. The questionnaire retains a two item "Positive" (items # 11, 12) and a four item "Negative" scale (items # 1,4,6,8), measuring respectively reasons for and barriers to having a mammogram. In the present sample, the "Positive" scale had a test-retest correlation of 0.22. The "Negative" scale had a test-retest correlation of 0.52. Tests for internal consistency of each of the four modified scales were acceptable for short forms, 0.60 to 0.8. Low test-retest correlation for HBQ and MDB scales are expected, given that educational interventions were intended to affect these outcomes.

The BFQ-revised is a set of 10 true/false and 5 multiple-choice items covering knowledge of breast cancer risk factors and early detection facts. In the present sample, the BFQ "Knowledge" scale had an internal consistency of 0.46, and a test-retest correlation of 0.17. The low internal consistency of the BFQ which sums weakly correlated items is expected since each item taps a different key idea.

BSE proficiency was measured by direct observation. PE were observed at pre-test before training, and a post-test immediately after training. Direct observation of technique awarded one point for each of ten items stressed on the Lange@ video: inspection with arms up, leaning over and hands on hips; palpation with 2 or 3 finger pads, small circles and gentle, medium and deep pressure; systematic search pattern; coverage of entire upper chest and the axilla; squeezing the nipple. Accuracy was determined by having each participant examine two gel breast models of differing consistency, each with five lumps of one centimeter or less. The number of correct lumps was recorded as well as the number of false positives. Two raters (MR, VW) performed all the observations. Inter-rater reliability in scoring BSE observation was K=0.8.

5. Preliminary Results

Results at this time are preliminary. The analysis presented here reflects complete data entry through July 1999, however the data is rough and has not been thoroughly cleaned. Table 1 presents a first cut of the pooled 7 agencies comparing peer educators at pre- and post-test with a volunteer sample of community women completing the same protocol. T-tests for independent samples are presented. Paired analyses were not done. P-values are 2-sided.

Table 1: Training Effects Comparison of Peer Educators Pre- and Post-Test With Peer Trained Community Women: Mammography Decisional Balance (MAMNEG, MAMPOS), Health Beliefs (HBFEAR, HBEFFIC) and Breast Facts (REVFACT)

GROUP	MAMNEG	MAMPOS	HBFFEAR	HBEFFIC	REVFACT
PE-t_1 (N)	84	84	76	67	30
X(SD)	6.8(2.9)	12.8(2.4)	13.9(3.8)	17.7(2.2)	14.9(2.4)
PE-t_2	207	206	206	203	133
Z(SD)	6.4(3.4)	13.7(1.9)*	13.8(3.6)	18.2(2.8)**	15.0(1.9)
ComW (N)	247	248	241	226	188
X(SD)	6.2(3.2)	13.4(2.5)	14.4(3.6)	18.6(2.2)	15.4(1.8)*

* $p<.05$; **$p<.01$

These data suggest that in a motivated group of women such as the PE, an educational program delivered by health professionals significantly increased positive values regarding mammography and increased self-efficacy for breast screening. Fear of breast cancer was unchanged by our intervention and negative decisional points for mammography declined slightly though non-significantly. These findings are consistent with our hypothesis that a culturally competent, literacy-independent intervention would promote self-efficacy and support perceived positive screening attitudes. Consistent with our earlier work, barriers to mammography did not decrease nor did fear increase. This is particularly interesting in light of a recent report in which an individual educational intervention resulted in decreased adherence among low education women.[6] Further analyses (ANCOVA) will control for the effects of education, marital status and duration of US residence on outcomes. Once we have linked the attitudinal data to the SOA follow-ups we will be

able to test the association between beliefs and behaviors. Comparing community women (ComW) to PE, no significant differences in MDB or HBQ scores are observed between the ComW and the PE who delivered the intervention. This suggests either a strong selection bias in that PE approached women already favorable to their message; that only women favorable to the message volunteered for research participation or that the PE were successful in promoting pro-screening beliefs and attitudes. Without pre-testing of the ComW this cannot be determined with certainty. We do in fact have some such data, but it is not ready for presentation. Finally, we see that no significant change in REVFACT is seen for the PE. Nonetheless, ComW perform as a group significantly better than the PE. The sample sizes are quite large for this measure and the absolute difference in scores is quite small. We plan to undertake a further analysis of items which may explain this unexpected finding.

6. Problems

In general, the oversight of the project has improved with experience. A continuing problem is the retention of PE. We attach the report of a consultant in lay health education who assisted us in the process of self-evaluation. The PE have identified several problems which we are addressing. The first is feeling unqualified to present themselves as "experts." This has been particularly true the Chinese women for whom cultural values place great weight on formal education. For these women working in groups at "breast parties" held at the agency has been a partial solution. In other groups, patriarchal family traditions have influenced retention. Husbands have in several cases objected to women taking time away from home and family for community activity. In other cases, husbands have felt that if time was available for work, this should be at a paid job. Thus volunteerism is difficult concept in

predominantly poor, immigrant families. Furthermore, immigrant families are highly mobile. Several excellent PE had to resign when the families moved out of town to join relatives. We have found then that 2 or 3 highly motivated PE, supported by their families, are more productive than a larger number of women with less ability to commit to the project. In one case, ECAC, only one PE is consistently active. She has won the support of her agency and her family by being hired as part-time staff by the agency for this work. She is uniquely connected in her community, being highly respected at the mosque and fully bilingual in Somali and Amharic. As a result of this project she has enrolled in ESL classes. Two agencies (AIHS and AHS) sought and obtained additional outside funding to expand PE activity in women and children's health.

As originally proposed, a sample of 350 ComW are needed to test the main hypotheses. We are currently within about 100 subjects of meeting this goal. There are however, several problems to be resolved. First, follow-up has been less rigorous than we would have desired. This partly due to the HA truly understanding the requirements of research, partly due to the mobility of the populations (no telephones, frequent moves) and partly due to our inability to access medical records of participants to confirm self-reports. As noted above, over 400 mammograms have been performed as a result of this project. All of these women had their mammograms through the intervention of the HA in that they had heard about the project but many did not actually participate in an educational intervention. Thus their motivation for screening remains unmeasured. The extent of volunteer bias among participants then cannot be accurately estimated. If we are to go to the next step in promoting screening adherence, it will be important to identify factors which

differentiate the one-time screenees from those who go on to practice periodic screening. [7]

7. Conclusion

Peer education appears to promote breast screening adherence among low-literacy non-English-speaking immigrant women. Preliminary data suggest the intervention strengthens self-efficacy and pro-mammography beliefs while having little effect on perceived barriers to mammography or fear of breast cancer. The impact of factual information is unclear. Further research is needed to clarify culture-specific patterns and to improve our understanding how the peer process affects adherence to breast screening guidelines.

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Project 3: Breast Health Education for Minority Providers

PI: Monica Morrow, M.D.

INTRODUCTION

The purpose of this study is to improve the knowledge level of minority health care providers regarding breast health and breast screening practices and to teach these providers the proper technique of breast examination. Studies have demonstrated that even among women with a regular source of medical care, 25% to 50% had not had a breast examination by a health care provider within the past year, and 50% to 75% of women over 50 had not had a mammogram.[1] Breast health screening was especially infrequent among women with less than a high school education or a household income below $15,000. Patient awareness of breast cancer risk and a recommendation by a health care provider to undergo screening mammography have been demonstrated to improve patient compliance.[2,3] For many women, nurses serve as a major contact point with the health care system. However, a minority of nurses regularly perform breast examinations, and 37% of 2,800 registered nurses reported knowledge deficits regarding breast cancer risk factors and signs and symptoms of breast cancer.[4] This information suggests that breast health education programs for nurses caring for medically underserved women have the potential to increase the utilization of breast cancer screening tests in this patient population.

SCOPE

The participants in this course are nurses employed by the Chicago Department of Health Clinics, the Erie Family Health Center, and the Winfield Moody Health Center. These sites together see approximately 440,000 underserved patients annually and

have no funds for continuing medical education of nurses. The educational intervention is conducted in a small group format and includes a baseline assessment of knowledge using both a written test and a standardized patient. The intervention consists of small group lectures and "hands-on" instruction in breast self examination (BSE) using models. A written post-test and the performance of a breast history and physical examination an a standardized patient at the completion of the course are used to assess the immediate impact of the intervention on behavior. Patients are recalled one year after completing the course to assess skills retention, again using both a written examination and a standardized patient.

WORK TO DATE

A. Course Participants

Nine courses have taken place, with a total of 99 participants completing the course. Self-reported information on age, ethnicity, education, and work experience for the participants was collected. The mean age of participants was 45 years, with a range of 23 to 68 years.

	n	
Ethnic Background		
African American	55	(55.5%)
Hispanic	20	(20.2%)
Caucasian	18	(18.2%)
Asian	3	(3.0%)
Other	2	(2.0%)
Not Stated	1	(1.0%)
Highest Degree Attained		
LPN	7	(7.1%)
RN	74	(74.7%)
MS	8	(8.1%)
PhD	2	(2.0%)
*other (healthcare advocates)	8	(8.1%)
Years of Work Experience		
<5	27	(27.3%)
5-10	17	(17.2%)
>10	55	(55.6%)

B. Results of Intervention

Of the 99 participants, 79% (n=78) stated that they instruct women on breast self-examination and 73% (n=72) indicated that they teach the American Cancer Society breast cancer screening guidelines to their patients. Pre- and post-test scores are summarized below. At course entry, 54 participants (55%) scored at the 75th percentile or higher. At the end of the intervention this increased to 84 (85%), an

increase of 30%. All participants had pre- and post-intervention scores for the standardized patient exam. Eighty-three (84%) of the students improved, and 6% (n=6) demonstrated no improvement as determined by the number of areas correctly examined. The most common deficiencies observed in the clinical breast exam were not supporting the arm when examining the axillary nodes, failure to search all the breast tissue, failure to apply light to deep pressure when palpating the breast, and not performing the exam with the patient both sitting and lying down. Failure to examine the superclavicular nodes was a common problem observed in previous years, but this has improved due to increased attention to this matter by instructors. The written tests covered seven areas of breast health knowledge: risk factors, breast self-exam, screening, symptoms, diagnosis, treatment, and breast cancer facts. The largest deficit of knowledge prior to the class was in the "risk factors" area, which was composed of true/false questions such as "breast cancer develops only after age 50." Participants demonstrated the most knowledge prior to the class in the "breast self-exam" area (for examples of questions in each area, please see appendix).

Overall, 81 participants improved their individual numeric score by taking the class, it was unchanged in 9, and decreased in 9. Those with lower test scores usually answered two additional questions incorrectly. Although all knowledge areas saw improvement on the post-test, participants showed the most improvement in the "risk factors" knowledge area (30%) and also showed significant improvement in the "treatment" (16%) and "diagnosis" (13%) areas.

Thirty-one healthcare providers returned for re-testing 12 months or more (mean = 14 mo.) after completion of the intervention. On the re-test, 6 students improved their

score compared to their post-test, 4 stayed the same, and 21 saw a decrease in score. Of the students whose scores decreased, 7 scored above the original pre-test, 1 scored the same, and 13 scored below their original pre-test.

Retention was most pronounced in the "breast cancer facts" area, which showed only a 0.1% loss of knowledge. "Risk factors" and "screening" saw the least retention, with 16% and 12% losses, respectively.

	% of students answering questions correctly		
Knowledge Area	Pre-test	Post-test	Re-test
Breast Self-exam	90.6	94.7	90.3
Symptoms	79.5	86.0	84.4
Breast Cancer Facts	76.7	82.5	82.4
Diagnosis	75.8	85.8	88.5
Screening	75.8	84.1	74.4
Treatment	70.3	81.8	78.1
Risk Factors	62.0	80.3	67.1

A detailed analysis of the individual questions and their performance identified several that were ambiguous, and these will be deleted from subsequent exams.

Re-testing on the standardized patient revealed that 14 students improved proficiency compared to that demonstrated at the completion of the course, 4 were unchanged, and 13 showed decreased proficiency. Of those students whose proficiency went down, 7 were more proficient than their original baseline assessment, 4 stayed the same, and 2 were less proficient than their baseline assessment.

Course participants were asked to rate the course on a 5-point scale for its utility in increasing their knowledge and relevance to their practice, and all ratings continue to be in the upper 2 categories.

CONCLUSIONS

The results of this study clearly indicate that a low cost, small group educational format is effective in improving participants' knowledge of breast heath and screening, as well as their breast examination skills, in the short term. Follow-up re-testing thus far has indicated that overall, knowledge levels were slightly improved in all areas of the written test compared to pre-test scores. As anticipated, there was a decrease in test scores compared to what was seen immediately after the intervention. In contrast, breast exam proficiency was in most cases retained, and in almost half the cases even improved with the opportunity to practice. Continuing data on the long-term retention of skills will be important to obtain. In year 3 of this project, we again saw a low pre-course dropout rate, due mostly to confirmation notices and reminder calls placed a week before the course. We also saw an increase in the number of participants returning for follow-up re-testing. This may be attributed to incentives such as a buffet luncheon, and repeated efforts to contact past students. Sufficient data has been obtained on the performance of individual questions in the test pool to allow those that perform poorly to be deleted. In addition, curriculum modifications to emphasize those knowledge areas where all students perform poorly will be made in year 4.

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Project 4: Increasing Adherence to Physician's Screening Mammography Recommendations:

A Randomized Controlled Clinical Trial

PI: Nancy Dolan, MD

Introduction

In a pilot study conducted in Northwestern Medical Faculty Foundation general medicine practice we identified two separate steps in the process of adherence; 1) acceptance of the recommendation, and 2) completion of the intended test, each with it's own barriers. [1] Women who refused the test were older and were more likely to think mammography was unnecessary. Women who agreed to the test but failed to adhere often cited reasons on inconvenience. As a follow up to this study, in year one of the grant we completed a randomized clinical trial in the same practice site to test an intervention aimed to reduce barriers of the adherence process. The results are reported in a 1999 issue of Archives of Internal Medicine.[2] Two hundred and forty-one patients were assigned to the control group and 210 to the intervention group. Seventy (30%) of the intervention group received a same day mammogram. Their mean satisfaction level with the experience was high; 96% stated they would take advantage of this opportunity in the future if it were available. Three months after the recommendation was made, 58% of those in the intervention group had obtained the mammogram compared to 46% of those in the control group (p=< 001), increasing to 61% and 49% respectively at six months (p = <0.001). Three-month adherence rates were higher in the intervention group compared to the control group for all subgroup analyses except for the subgroup of women who had had three or more mammograms

within the past five years. In summary, same day mammography availability increased adherence rates and was associated with high levels of satisfaction.

The current phase of the study has two parts: Part one is to test the generalizability of the above results to other practice settings. Specifically the study is testing the effectiveness of a two-intervention strategy of targeted educational messages and same day screening mammography in a private practice and a public health clinic. Part two is to qualitatively assess breast cancer screening knowledge and attitudes of the subset of women from the first part of the study who have not gotten the recommended mammogram within one year of the recommendation. The study population consists of female patients age 40 - 79 presenting for appointments at two different practice sites in the Chicago area; 1) a private practice site with 7 physicians, and 2) a City of Chicago public health clinic. Same day mammography screening is available to patients at each of these practice sites. Physicians, practice managers, and receptionists at each site have been oriented with regard to study logistics, patient enrollment, and data collection.

Year 3 Objectives:

1. Continue follow up data collection via chart review at three, six, and twelve-month intervals, and phone calls to participants twelve months after enrollment (if chart review does not indicate follow through with doctors recommendation for a mammogram).

2. Begin implementation of focus groups and refinement of target messages.

Randomized Control Trial

Study enrollment was completed at the private practice site in March 1999. One hundred and twenty women have been enrolled and follow up data is being collected via chart review and phone calls to those women who are at the one-year mark in the study. The public health clinic continues to enroll participants. To date 166 of the expected 200 participants have been enrolled. Follow up data is being collected on those women at this site. Follow up data is collected via chart review and is conducted at three, six, and twelve-month intervals. Phone call follow-up is being conducted after twelve months if chart does not indicate follow through with doctor's recommendation for a mammogram.

Over the past year there has been one variation in the study endpoint of the project as proposed. Power calculations were redone based on new estimates of baseline rates of mammography use in each practice site. The initial number of desired patient were 323 in the public health clinic, and 120 in the private practice group. After re-assessment of the public health clinic's baseline rate of mammography use, the target number of desired subjects changed from 323 to 200, while the desired number of patients in the private practice site remained at 120. This brings the target endpoint to a total of 320 subjects.

To date enrollment at the private practice site has been completed with 120 participants enrolled. At the public health clinic enrollment is at 166 of the expected 200 participants. Preliminary data analysis has been started on data collected from both sites. The following tables summarize demographic data on the study population for each of the two study sites.

Characteristics of Intervention and Control Groups
Private Practice Study Site

Characteristics	**Study Participants**
Group Assignment (%)	
Intervention	50%
Control	50%
Mean age + SD, years	57 + 11.03
Education, years (%)	
Up to high school	24%
Some college	26%
College graduate	50%
Race (%)	
Caucasian	77%
African American	16%
other	7%
Primary Insurance (%)	
Medicare	29%
Private/non HMO	49%
HMO	20%
Medicaid	2%
Marital Status (%)	
Single	20%
Married	44%
Widowed	15%
Divorced / separated	21%
Intend To Get Mammogram Within 3 Months (%)	
No	2%
Yes, definitely	94%
Considering	4%
Mammogram Within 3 months (%)	
Intervention	55%
Control	45%

Characteristics of Intervention and Control Groups
Public Health Clinic Study Site

Characteristics	**Study Participants**
Group Assignment (%)	
Intervention	48%
Control	52%
Mean age ± SD, years	65 ± 10.09
Education, years (%)	
Up to high school	88%
Some college	11%
College graduate	1%
Race (%)	
Caucasian	3%
African American	95%
other	2%
Primary Insurance (%)	
Medicare	76%
Private/non HMO	1%
HMO	12%
Medicaid	11%
Marital Status (%)	
Single	18%
Married	17%
Widowed	36%
Divorced / separated	29%
Intend To Get Mammogram Within 3 Months (%)	
No	18%
Yes, definitely	55%
Considering	27%

Focus Groups

The focus group phase of the study has been delayed from year three to year four of the study. We anticipate that this phase of the study will begin September 1999. The university's Internal Review Board recently approved the focus group methodology.

The purpose of this phase of the study is to qualitatively assess breast cancer screening knowledge and attitudes of the subset of women from the first part of the study who have not gotten the recommended mammogram within one year of the recommendation. As prior studies have noted, patient perceptions play an important role in affecting behaviors influencing the early detection of cancer. Defining these perceptions in this particular patient group, is an important step toward improving breast cancer screening.

Women will be randomly selected from the intervention and control groups and will be invited by mail to participate in a focus group on breast cancer screening. Six focus groups of 6-8 women will be conducted. The information gained from the focus groups will be used to develop future educational interventions for this population. We will also use feedback from the groups to further refine the targeted messages used in the larger study.

Key Research Accomplishments

- Publication of initial trial results in Archives of Internal Medicine.
- Successful enrollment of new study cohorts in a private practice setting and a public health clinic

Conclusion

Enrollment for the clinical trial has been completed at the private practice and is near completion at the public health clinic, two very different practice sites with unique patient populations. The target number of women to be enrolled at the public health clinic has been reduced from 323 to 200. Follow up data collection is ongoing and will continue until subjects have either had a mammogram or until one year after the last patient is enrolled. The initiation of the focus groups has been delayed but is anticipated to start September 1999.

Reportable Outcomes

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PROJECT 5 - Mujeres Felices por Ser Saludables: Happy Healthy Women.
A Breast Cancer Risk Reduction Program for Premenopausal Hispanic Women.

PI: Marian Fitzgibbon, Ph.D., Susan Gapstur, Ph.D.

INTRODUCTION

The incidence of breast cancer is consistently higher among non-Hispanic whites than Hispanics (Eidson et al, 1994, Trapido et al, 1994). However, data suggest that between 1969 and 1987, the incidence of breast cancer increased more rapidly among Hispanic (57%) compared to non-Hispanic white women (15%) (Eidson et al, 1994). This change in Hispanics may be due, at least in part, to increased screening and/or to temporal changes in lifestyle factors such as diet.

Mujeres Felices por Ser Saludables is a randomized intervention project designed to assess breast cancer risk reduction behavior among 330 young Hispanic women living in Chicago. **The specific aims of the study are:** a) to conduct an 8-month, weekly active intervention that promotes a low-fat and high fruit and vegetable diet, and provides instruction about breast self-exam (BSE) and other aspects of early breast cancer detection and breast cancer risk; and b) to measure changes from baseline in dietary intake based on nutrient data assessed from three 24-hour dietary recalls, and to measure changes from baseline in serum carotenoids and fatty acid levels, frequency of BSE, and anxiety related to BSE at 8-months post randomization.

The major accomplishments during Year 03 of the study were: 1) timeline revision [see Statement of Work p. 6]; 2) ongoing recruitment, baseline health center visits, and

intervention classes; 3) randomization of 177 women into classroom and mail groups; 4) collection of 8-month follow-up data on 81 women; and 5) establishment of subcontracts. The continued integration into the environment of the Erie Family Health Center (EFHC) has helped to foster a sense of trust with prospective and current participants.

BODY

A. Methods and Procedures

1. Overall Study Design: In this study, 330 eligible women will be recruited to participate in the study. Data are collected at two Health Center Visits: baseline and 8-months post-randomization. After the Baseline Health Center Visit, eligible and willing participants are randomized to either the classroom group or to a mail control group. During the first 8 months (i.e., active intervention), the women in the classroom group attend 16 sessions in which the curriculum integrates dietary and breast health education. The goal is to achieve adherence to a low-fat/high-fiber diet and to increase behaviors consistent with good breast health.

2. Participant recruitment: Our primary recruitment efforts have focused on Hispanic/Latina women who utilize services at EFHC. Hispanics account for 83% percent of the population who use their services. In addition, Latina women who attend the Women, Infant and Children Program at the Chicago Nutrition Center near EFHC are invited to participate.

Recruitment for the project began in June 1997. Through June 1999, one thousand eight hundred and twenty one women had been contacted either by telephone or in person. Approximately, 17.7% (i.e., n = 323) met the initial screening eligibility criteria and agreed to complete the Baseline Health Center Visit. Pre-eligibility criteria include: a) aged 20-40 at baseline; b) not currently pregnant or lactating; c) not planning a pregnancy within the next two years; d) no personal history of diabetes or cancer; e) Hispanic; and f) > 28% calories from fat intake.

3. Health Center Visits: Of the 323 women who were eligible for the Baseline Health Center Visit, 259 completed the initial phase of Health Center Visit. Thirty-six dropped out after this phase and 46 were ineligible (i.e., body mass index (BMI) > 35 kg/m^2, eating disorder or serum cholesterol > 260 mg). Of the 259 who came to the first phase of the Health Center Visit, 177 completed the visit (including all three baseline 24-hour diet recalls) and were eligible for randomization. Presently, 87 women have been randomized to the intervention and 90 to the mail control group.

Through June 1999, 97 women were scheduled to complete the 8-month Health Center Visit. Of those 97 women, 16 (17%) dropped out prior to the Health Center Visit and 81 (83%) completed the initial phase of the 8-month Health Center Visit. More importantly, 70 women (72%) completed the entire Health Center Visit, including all three 24-hour diets recalls. The percentage completion of 72% is an increase from 58%, which was our retention rate prior to the implementation of our enhanced recruitment and retention efforts.

4. Data Management and Quality Control: Data management and quality control continue as described in our 1998 Progress Report. This includes almost daily data entry and verification and quality control procedures for the dietary data, anthropometric measurements, and laboratory assays. Data analyses have been initiated to verify that at baseline there are no differences between the classroom and mail groups in age, BMI, acculturation, education, number of live births, and dietary and breast self-exam measures that are described in Table 2.

To monitor potential laboratory drift, the within-day and between-day reliability of the laboratory assays for serum cholesterol levels are assessed using blinded split samples on approximately 10% of the women screened. Overall, the intra-individual within-day coefficient of variation is 1.6% (n=34 samples), and the intra-individual between-day coefficient of variation is 2.4% (n=18).

5. Intervention: Table 1 describes the number of women randomized to the classroom intervention group and to the mail control group through June 1999. The women randomized to the classroom intervention have been divided into eleven groups, and the intervention is delivered in either English, Spanish, or for group 5 both English and Spanish.

Starting January 1998, the first classroom group began intervention sessions. Subsequently, a new group starts intervention sessions approximately every six weeks. The comparable mail control group receives health related material (e.g., safety belt use) at intervals equal to those the classroom group attends the intervention sessions. These health-related materials do not include any information related to diet or breast health.

Table 1. Distribution of women by intervention and control group.

Group number	Number of women Classroom	Control	Number of intervention sessions completed	Spanish/English
1	7	7	16	Spanish only
2	4	6	16	English only
3	4	6	16	Spanish only
4	7	5	16	Spanish only
5	7	8	16	Spanish and
6	9	15	16	English
7	8	9	16	Spanish only
8	9	8	15	Spanish only
9	11	8	11	Spanish only
10	11	10	6	Spanish only
11	7	8	0	Spanish only
				Spanish only

B. Preliminary Results

1. Baseline Descriptive Data: Of the participants who have been randomized, complete data were entered and verified for 167 women through June 1999. Table 2 shows the sociodemographic, cultural and anthropometric characteristics of these women. The age of the women ranged from 20.9-40.9. The majority of the women were not born in the United States, and the data indicate that most of women who have been randomized were born in Mexico (data not shown). Using the acculturation index developed by Marin & Marin (scale of 1-5, with 1 as low acculturated), the average acculturation level of these women is very low. More than half of the women did not graduate from high school (64%). A high proportion of the women are currently married (75.4%). The average body mass index of the women is 27.5 kg/m^2 indicating a high proportion of these women are overweight despite our cut-off of 35 kg/m^2 for eligibility. In addition, these data suggest that motivation to participate in the project does not result from a positive family history of breast cancer, as only two women reported a family history of breast cancer. The average serum

cholesterol for these participants is within acceptable range for this age group of women. Finally, only 15.6% of the women reported current oral contraception use, and 13.8 % are currently smoking cigarettes on a regular basis.

Table 2. Baseline sociodemographic, and anthropometric characteristics of the randomized participants (n = 167).

Characteristic		Characteristic	
Age; mean ± SD	31.1 ± 5.2 years	Body mass index; mean ± SD	27.5 ± 3.9 kg/m^2
Country of birth; n (%)		Family history if breast cancer; n (%)	2 (1.2%)
United States	21 (13%)	Yes	157 (95.0%)
Other	146 (87%)	No	8 (4.8%)
		Don't Know	
Acculturation index; mean ± SD	1.6 ± .88	Serum total cholesterol; mean ± SD	175 ± 32 mg/dl
Education; n (%)		Current oral contraception use; n (%)	26 (16%)
≤ High school	107 (64%)	Yes	141 (84%)
> High school	60 (36%)	No	
Marital status; n (%)		Cigarette smoking; n (%)	
Single, never married	27 (16%)	Never smoke regularly	144(86%)
Currently married	126 (75%)	Current smoker	23(14%)
Separated/divorced	14 (8.4%)		
Number of live births			
1-2	85 (51%)		
3-4	67 (40%)		
5-6	5 (3%)		
missing	7(4%)		

2. Baseline dietary intake and breast health: The average daily dietary intake as assessed by three 24-hour diet recalls are reported in Table 3. These data were computed for 123 women who are in process, and completed three recalls which were examined for quality control. Average total daily calorie intake ranged from a minimum of 798 kcal to a maximum of 4,374 kcal, and average total daily fat intake ranged from 19.8 to 172.7 grams. It is interesting to note that

total fiber intake is high (i.e., 20 grams per day). Furthermore, using a measure of stage-of-change for fruit and vegetable intake, the data indicate that more than 77.2% (n= 129) of the women were motivated to make preliminary changes in their fruit and vegetable consumption. This level of motivation is ideal for compliance with the dietary intervention. In addition, table 3 shows data regarding BSE proficiency and utilization of breast care in the 167 women randomized. No woman correctly performed a breast exam on the breast models. In addition, the model contained 5 lumps and only 5.1% of the participants were able to detect at least 5 lumps. One woman reported finding 6 lumps, however she may have counted one lump twice. The proportion of women who ever practiced BSE was 62%. In addition, according to the stage-of-change scale, slightly more than 49.1% (n=82) of the women are considering beginning BSE, whereas 27% are routinely practicing BSE on a monthly basis.

Table 3. Baseline dietary (n= 123) and breast health (n=167) characteristics of the randomized participants.

Characteristic		Characteristic	
Average daily intake; Mean ± SD	1943 ± 504	Ever practiced BSE; n (%)	
Total energy (kcal)	kcal	Yes	104 (62%)
Total fat (g)	66 ± 24 g	No	63 (38%)
Total carbohydrate (g)	275 ±73 g		
Total protein (g)	69 ± 19 g		
Total fiber (g)	20 ± 6.6 g		
Average daily percent calories;		Ever had a clinical breast exam; n (%)	117 (76%)
Mean ± SD	30 ± 5.2 %	Yes	45 (23%)
Fat	57 ± 6.2 %	No	5 (1%)
Carbohydrate	14 ± 2.5 %	Not sure/missing	
Protein			
Breast self-exam technique; n (%)	88 (53%)	Ever had a mammogram; n (%)	
Not circular motion	73 (44%)	Yes	19 (11%)
		No	148 (89%)

Circular motion/lose contact	4 (3%)	
Circular motion/constant contact		
Number of lumps found; n (%)	87 (53%)	
0	49 (29%)	
1-2	25 (15%)	
3-4	4 (2%)	
5-6	2 (1%)	
Missing		

3. Intervention: As described earlier, eleven groups of women have been randomized to receive the intervention. The timing and presentation of the material varies as a function of the language spoken. To date, we have had only one group delivered completely in English and one group delivered in both Spanish and English. The others have been delivered in Spanish. The Spanish-speaking groups tend to be lower in acculturation, and the women verbalize more concerns related to immigration, feelings of isolation, transitional living difficulties, finances, child rearing problems, and other stressors. At times, this can make it difficult for the interventionists to deliver the curriculum material. However, when women have a chance to voice their concerns, they feel less anxious and are then able to attend to the material.

Groups 6-10 began during Year 03. The content of the curriculum has not changed, but we implemented several changes in how we conduct the groups. First, there are now 16 sessions rather than 20 sessions due to the shortening of the overall intervention to 8-months The first 12 sessions cover the bulk of the material. The final groups were designed as repetition and consolidation of knowledge. Second, we now extend an open invitation to friends or family members of current participants to help foster motivation and better attendance, and maintain stability and cohesion in the groups. Third, we offer incentives to participants for referring prospective participants. Fourth,

thank-you parties are held for both classroom and mail participants at the end of the intervention.

Our experience with the integration of the breast health and nutrition curriculum has proven very rewarding this year. The interventionists are more experienced with the curriculum and are more comfortable being flexible with the timing and emphasis of each session, depending on the needs of the group. The primary issue verbalized by the women related to dietary change is how to get their families to accept the changes. They indicate that changes in types of food, food preparation methods, or the taste in foods are usually not accepted by either their children or spouses. However, many of the participants are still eager to learn new methods of preparing foods in a more healthful way.

Contrary to our initial impression, the majority of women are enthusiastic to learn more about breast health and the structure of the normal breast. This, at times, seems more interesting than the development of breast diseases. More specifically related to our specific aims, it is apparent that most of our participants have heard of BSE but really didn't know what they were looking for when performing it. They also have little experience talking with their health care provider about the subject. Even women who have had clinical breast exams were unsure what questions to ask. Dr. Oviedo (a breast surgeon) who is a speaker at one of the sessions and has given the women the opportunity to ask question that they might not otherwise have asked a health care provider.

The group sessions seem to be a forum for women to discuss their family's reactions to their participation in a program to change health behavior. Some women have said

that their husbands are not supportive of their participation in the program. For example, one husband said, " What are you going to get or learn from those sessions?" Some women felt that their partners reacted this way because of a belief that if you address the problem you are more apt to get the disease. However, other women have said that their husbands are very supportive and encourage their attendance in the program. Overall, it appears there is a mixed reaction to participation in the program. We have also now completed a sufficient number of groups to clearly see that each group creates their own dynamic. Some of the groups are more connected to each other and the interventionists. They enjoy the discussions, bring family and friends to participate on the sessions, and attend regularly. Other groups are less connected, more quiet, and often look to the interventionists to guide them

We have now completed seven groups. Our experience continues to strongly suggest that the delivery of the intervention needs to be tailored to the level of literacy and acculturation of the participants. We have observed that the lower the acculturation level, the more life stressors seem to impact the participants' ability to attend to the material. A strong connection with the interventionists continues to be essential if women are going to feel a bond with the group. Overall, the participants are enthusiastic and motivated to learn more about healthy ways to eat and take care of their bodies

C. Statement-of-Work (Timeline):

As mentioned previously, our goal is to recruit 330 women into Mujeres Felices por Ser Saludables, and retain these women for 8 months. We have made presently randomized 177 women and conducted 8-month follow-up visits on 81 women. We feel that the decision to change the study design to include a baseline and 8-month follow-up visit, but not a 20-month follow-up visit allows us to answer our primary hypotheses and

still retain the maximum number of women possible. Otherwise, our recruitment and retention efforts would be seriously diluted. Our recruitment (approximately 8 participants per month) and retention (72%) are stable and we will be able to meet our initial goal of 330 women randomized by the end of February, 2000. Based on the data collected over the last year, we have demonstrated the continued ability to continue to collect high-quality data of a unique nature (epidemiologic, behavioral, nutritional and laboratory) from this hard-to-reach population and retain them for an 8-month intervention. The interventionists deliver a novel and integrated nutrition/breast health curriculum that has enough flexibility to tailor it the language and acculturation needs of the participants.

CONCLUSIONS

The major accomplishments of this study during the last year include the recruitment and randomization of 177 Hispanic women into Mujeres Felices, participation of 11 groups of women, conducted 8-month follow-up visits on 81 women as of June 1999, and establishment of the subcontracts. Once women are randomized, retention in the study is high. We have integrated the breast health and nutrition curriculum, and have adapted the intervention to the education and acculturation levels of the participants. To our knowledge, this is the first randomized trial to deliver an integrated nutrition and early detection curriculum focusing on breast cancer. The feedback we have received from the participants continues to be extremely positive.

A goal, which we have continued to meet, is to be fully integrated into the day-to-day operations of EFHC. In this way, the aims of our study are consistent with the mission of the Health Center. The importance of nurturing trust between academic institution and

the community-based intervention sites cannot be underestimated in this type of research.

Reportable Outcomes:

Knight, S. J., Gapstur, S. M., Fitzgibbon, M. L., Losada, A., Blackman, L. R., Hogan, K., DeLa Torre, G., Avellone, M. E. (SBM, 1999). Breast self-examination in Hispanic women: Criterion related validity of a stages of change measure.

Fitzgibbon M.F., Knight S.J., and Prewitt , E, (SBM, 1998). Minority communities: Are they really hard to reach?

Fitzgibbon M.F., (1997). Interventions in minority communities. Grand Rounds, NUMS

Knight, S.J. (APA, 1997). Group strategies in breast cancer risk reduction for Hispanic women.

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PROJECT 6: NETWORKED BREAST CANCER CONFERENCE

PI: William J. Gradishar, M.D.

OVERVIEW

The purpose of this project was to explore the use of teleconferencing technology to provide multidisciplinary medical expertise to physicians treating breast cancer patients at six hospitals in the greater Chicago area. The hospitals are all members of the Northwestern Care Consortium. They are:

- Evanston Hospital (Evanston, Illinois)
- Swedish Covenant Hospital (Chicago, Illinois)
- Silver Cross Hospital (Joliet, Illinois)
- Ingalls Memorial Hospital (Harvey, Illinois)
- Highland Park Hospital (Highland Park, Illinois)
- Northwest Community Hospital (Arlington Heights, Illinois)

The multidisciplinary expertise was provided by physicians and staff at the Robert H. Lurie Cancer Center (LCC) and the Lynn Sage Breast Cancer Center of Northwestern University in Chicago, Illinois. An existing venue, the weekly Breast Cancer Conference at Northwestern, was expanded, via teleconferencing technology, to make it available to physicians from the participating hospitals.

The project was one of several individual activities under Cooperative Agreement DAMD17-96-2-6013, "Increasing Access to Modern Multidisciplinary Breast Cancer Care," between the U. S. Department of the Army and Northwestern University. This

was "Project Number Six – Networked Breast Cancer Conference." The Principal Investigator (PI) for the Cooperative Agreement is Monica Morrow, M.D., Director of the Lynn Sage Breast Cancer Center. The PI for Project Number Six was William Gradishar, M.D. The project was conducted via a subcontract issued to I. S. Grupe, Inc. (ISG), an Information Technology firm in Westmont, Illinois. Peter B. Schipma, President of ISG, directed the work performed by ISG. Other ISG participants were Mr. Robert Bouma and Ms. Lei Zheng. The period of performance for Project Number Six was originally scheduled for 22 July 1996 through 21 July 1998. However, extensive delays were encountered throughout the project (these are detailed in the discussion to follow) and ISG accepted a six-month, no-cost time extension to the subcontract, finishing the work in December 1998.

The project successfully demonstrated that multidisciplinary expertise could be shared across a wide geographic area using teleconferencing technology. The technology itself improved to a remarkable extent over the period from proposal submission to date. Indeed, the improvement was so rapid that the hardware and software capabilities actually deployed during the project were significantly better than had originally been proposed. Technology improvements continued throughout the project period, primarily in price/performance characteristics. Though the hardware and software obtained for use during the project was at the cutting edge of technology at project initiation, and remains state-of-the-art at the close of the project, similar capabilities can now be had for one-half to one-third the costs incurred by the project. This bodes extremely well for increased utility of teleconferencing in applications such as this.

Deployment of the technology was, however, quite a complex matter. All of the problems related to the telecommunications infrastructure necessary to support teleconferencing. All the hardware and software functioned as advertised upon

installation and we experienced no equipment failures throughout the project. The installation and operation of ISDN telecommunications lines was fraught with difficulty, delay and inoperability. So much time was lost to problems associated with lines that the project period had to be extended to accomplish the requisite tasks. Most of the ISDN line problems related to inexperienced personnel at the local carrier (Ameritech) and within the hospitals.

Utility of the teleconferencing capability and value from the medical perspective were widely variant. Acceptance by the Consortium member hospitals ranged from total apathy to extremely high enthusiasm. The extent of that spectrum can be illustrated by the facts that one hospital never participated in a teleconference subsequent to initial installation and testing, while another spent $12,000 of its internal equipment budget to upgrade the hardware so that its physicians could have more extensive participation. Many reasons underlie this variance in acceptance. They are detailed in the following discussion and provide insights into the possible barriers to deployment that must be addressed in future similar activities. The hospitals that participated actively did not present a sufficient number of breast cancer cases to provide a statistically significant analysis of effect upon medical treatment. However, the individual case data showed changes in treatment resulting from participation in the multidisciplinary conferences. Primarily these changes related to greater use of breast conservation strategies and greater participation in clinical trials. In addition, the physicians who participated regarded the results as highly beneficial. Perhaps the strongest endorsement of the medical value of this use of technology is the decision within the consortium to continue its use, to expand to other medical arenas and to increase the investment in the technology.

TECHNOLOGY

Teleconferencing Systems

The basic capabilities to permit teleconferences of meetings such as the Multidisciplinary Breast Cancer Conference, with participants at remote sites, have existed for decades. Until quite recently, however, costs have been virtually prohibitive. The contribution of recent technological advances has been that of providing teleconferencing capability at moderate cost. In effect, recent technological development has solved the bandwidth problem. A teleconference between two sites requires a television camera and a television receiver at each site. Cameras and receivers have been reasonably inexpensive for some time (the cost in current dollars is on a downward trend and the cost in actual dollars is perhaps one-tenth what it was a decade ago). But the telecommunications link between the sites has typically been prohibitively expensive. The problem has been the need for large bandwidth. A typical television image consists of approximately 500 by 300 pixels (picture elements), refreshed at a rate of 30 times per second (the actual situation, using analog signal generation, considering interlacing, including analog-to-digital conversion, etc., is considerably more complex, but this discussion presents the basic situation in reasonable fashion and with roughly appropriate numerical values). Each pixel must contain both color and intensity information, so we can assume the need for 24 bits (3 bytes) of information per pixel. Transmitting a full-motion television image thus requires moving 500 x 300 x 24 x 30 or 108 million bits per second (108 mbps) between the two participating sites. That calls for high bandwidth capability, which translates to a very expensive telecommunications line. Consider that a typical voice/data telephone line (often called POTS, for Plain Old Telephone System) has a bandwidth of approximately 56 thousand bits per second (56

kbps). The bandwidth need for television transmission is thus the equivalent of 2,000 POTS lines. The cost for that is simply too great.

Modern teleconferencing is done with one to four ISDN circuits. An ISDN circuit is effectively two POTS lines tied together, providing (with a little enhancement of the basic capacity of each of the two lines) a bandwidth of about 128 kbps. Television images of reasonable quality are therefore transmitted using only 1/1000th to 1/250th of that necessary for "regular" television. This is achieved through extensive computer processing of the television signal. In a typical television image, many pixels remain unchanged from frame to frame (a frame is 1/30th of a second). For example, in a common teleconference setting, two individuals hold a conversation, or one individual presents information to a class of viewers. In such situations, many parts of the image remain constant from frame to frame. The room, the furniture, etc. do not change. Current technology is based on that fact. Rapid computer processing of each frame determines which pixels change (the pixels forming the speaker's lips, for example, or those forming her arm as she makes a gesture) and which pixels remain unchanged. Only those that change need be retransmitted every 1/30th of a second. In this way a small fraction of the previously required bandwidth can provide reasonably good image transmission.

Telecommunications Infrastructure

Teleconferencing systems thus incorporate not only a television camera and television receiver, but also a computer to perform the extensive processing necessary to permit use of an affordable amount of bandwidth. The other necessary component is a reliable, high-quality telecommunications infrastructure that provides that bandwidth. Such an

infrastructure is now available in many locations within the U.S. (indeed, throughout the world). Except in certain rural areas, it is typically possible to obtain ISDN circuits, each comprising two high-quality POTS lines. Thus a single ISDN circuit costs only about twice the amount, in terms of installation costs, monthly fees, and use charges, that a normal telephone line costs. Currently, an ISDN circuit costs about $100 for installation, about $40 per month for basic service fees and about $0.50 per minute for usage. Higher quality images can be provided with greater bandwidth, so sometimes three or four ISDN circuits are combined. Even then the costs are extremely reasonable.

DEPLOYMENT

Selection of Hardware and Software

A major activity within the project was the selection of the most suitable hardware and software. Some equipment had been suggested in the proposal, and a budget had been established based upon those suggestions. By the time the project was actually initiated, that equipment was somewhat outdated. ISG staff members attended several of the weekly Breast Cancer Conferences and held discussions with Dr. Morrow, Dr. Gradishar and others to determine what needs had to be met. It quickly became obvious that any teleconferencing activities would have to be relatively unobtrusive and that they could not make inordinate time demands upon the Conference participants. Typically, a number of cases (often as many as 15 or 20) had to be considered at a given Conference. There were usually 30 to 40 participants in the Conference; the time of each of these specialists is a valuable commodity. Medical considerations always predominated; one case might get much more attention than others if it presented unusual circumstances or raised unusual questions. In light of all these parameters, the Conference has evolved to a rather neatly choreographed activity with a minimum of

wasted motion and talk. We were faced with superimposing a teleconferencing activity upon this infrastructure with a minimum of disruption and a maximum of efficiency for the physicians participating remotely.

Two general considerations became paramount after this analysis of the conduct of the Conference, and these were the basis for the overall set of decision parameters. The first was the necessity for unobtrusive operations that added minimal time requirements to the activities as currently conducted. The second was the use of the teleconferencing system to augment the normal activities of the Conference as well as providing remote access. That is, the system chosen not only had to add as little complexity, disruption and additional time needs to the existing smooth flow of Conference operations but, if possible, had to streamline the current activities so as to "make up" for the additional demands teleconferencing would place on operations.

ISG conducted an extensive analysis of available hardware and software, considering not only teleconferencing capabilities but also the parameters noted in the preceding paragraph and the budget for hardware and software. Because the quality of video and audio within actual teleconferences might have considerable impact upon the operations, we arranged to see each of the potential systems used in live teleconferences. As the quality of transmission was evaluated during these sessions, we also considered the complexity of operations that were necessary to conduct each conference.

There were two final contenders. These were PictureTel and VTel. In fact, either would have served the needs of the project. However, the VTel system was preferable because it had the simplest and most intuitive user interface. Unfortunately, this was

also the most expensive option and initially it appeared that VTel hardware and software could not be obtained within the equipment budget. However, we found that the equipment is marketed by vendors rather than by VTel directly and that discounting was common. In addition, we determined that we could obtain the PCs necessary for the SmartStations (the individual systems to be placed at each of the six remote hospitals) independently from a VTel vendor. The vendors marked up PCs considerably and charged a considerable fee for integrating the SmartStation hardware and software with the PCs. But PCs are generic, prices continually fall, and integration consists only of installing some boards and software and configuring the systems. Accordingly, we purchased the PCs separately and did the integration internally.

The system consists of a "Team Conference System" at Northwestern University and six SmartStations, one at each of the participating hospitals. The Team Conference System (TC1000) has several components. The major items are a PC that runs the VTel software and a large screen (69 cm diagonal) monitor. These are both mounted on a wheeled cart, as they are quite bulky. The main camera is mounted atop the monitor. It has pan and zoom capabilities, all remotely controlled. There are two ancillary input sources. One is a document camera, which is mounted on a stand that has both transmissive and reflective light sources. We used this for mammograms and ultrasound images, so the transmissive light source was used. The other input source was a photomicroscope, which was used to display pathology slides. Initially, the microscope signal was sent to a separate monitor, but then the remote sites could not view the pathology slides, and the attendees in the Library had to view two screens. So we took the signal from the photomicroscope as another input to the system. To make the task of the Pathologist simpler, we also sent that signal to a small-screen (13 cm diagonal) monitor that faced the Pathologist so that she could easily arrange her slides

and move them appropriately under the microscope. The other components of the TC1000 are an omni-directional microphone, speakers, a remote control for the monitor, a wireless (infrared) keypad/mouse and a control tablet. The latter proved to be an extremely valuable tool. From the tablet, using an electronic stylus, the "director" of the teleconference can choose input source, move the camera, pan and zoom, control picture-in-picture, change image sizes, etc. With a bit of practice, he or she can have the appropriate images on the screen at all times as the conversations proceed, with no disruption whatsoever of the participants in the conference. This is extremely important, in that it not only saves valuable time, but permits the teleconference participants to conduct their work without interference or special actions on their parts. Directors with a reasonable amount of practice could even anticipate the turns the conference would take (the structure is quite consistent from case to case) and switch to the appropriate image virtually simultaneously with the flow of the conference.

The SmartStations consist of a PC with speakers and a camera/microphone mounted on the PC monitor. These are very straightforward systems. The cameras are fixed in focus and direction. Whereas the TC1000 could be easily used in a room containing 30 to 40 participants, the SmartStations can only support about four or five users, because of the small screen size and the necessity to be close to the microphone. In practice it was typical for a hospital to have two or three persons participating, so the SmartStations were more than adequate. In each case, wires had to be run from the systems to wall-mounted RJ45 telephone jacks for connection to the ISDN circuits. Setting up the TC1000 takes about ten minutes; setting up the SmartStations takes only a couple of minutes.

Initial Education

The six participating hospitals are all members of the Northwestern Healthcare Consortium, but they are also autonomous organizations. Each has its individual goals and objectives. One of the early activities in the project was an educational effort to explain the project to the physicians and staff at the six hospitals and invite them to participate. There was no coercion, so that the true perceived value of the concept could be fairly evaluated.

ISG prepared a PowerPoint presentation that used text, graphics and photographs to describe the intent of the project and show potential participants how they would interact with the Multidisciplinary Team if they accepted the invitation to become active in the project. ISG then made presentations at each of the six hospitals. These typically consisted of a 15 to 20 minute presentation, supported by the PowerPoint slides, and a discussion period of 15 to 30 minutes. In some cases the presentation was made to a group of physicians (typically breast cancer surgeons) and in other cases to considerably larger groups, such as the Cancer Committees at different hospitals.

Installation

Installation of the teleconferencing systems was simple, rapid and virtually trouble-free. Installation of the ISDN circuits was complex, fraught with extensive delays and extremely problematic. In the following paragraphs we summarize the installation and testing of the teleconferencing systems and telecommunications circuits respectively. In terms of chronology, the teleconferencing systems were delivered, then considerable

time passed while ISDN circuits were installed and then the teleconferencing systems were actually installed and tested.

The vendor, MCI Telecommunications, delivered the TC2000 system for use in the Vanderzwicken Library at the Lurie Cancer Center directly to ISG. ISG personnel unpacked and checked all the system components and transported them to the Vanderzwicken Library. An installation session was arranged with MCI. The session took approximately one day, during which all the components were assembled, software was installed, and all operational activities were thoroughly tested. ISG personnel participated in all the setup activities and became completely familiar with operation of the TC2000. Test teleconferences were conducted with MCI sites and the TC2000 was certified for use over standard ISDN lines.

The vendor, MCI Telecommunications, delivered the six SmartStation teleconferencing system components directly to ISG. The remaining computer components used to support the SmartStations were separately delivered to ISG. ISG built the SmartStations from the various components. ISG also installed and tested the Operating System and SmartStation software in local mode operation. When the first SmartStation system was complete, ISG arranged an installation and training session with MCI Telecommunications. An MCI technician came to ISG's site and tested the system through teleconferences with MCI sites. The first system was certified and ISG personnel became familiar with all operational features of the SmartStation software. Subsequently, ISG personnel assembled and tested each of the remaining five SmartStations and had them certified by MCI prior to delivering them to the participating hospitals. ISG also trained the personnel at each of the six participating hospitals, as discussed in the following section. This methodology obviated the necessity of paying

MCI Telecommunications for six identical installation/training sessions that would have been redundant.

Installation of the ISDN circuits required the coordination of the local telephone company and each of the seven sites (Northwestern and the six participating hospitals). The local telephone company in the Chicago area is Ameritech. At the time of the initial installations, the Ameritech experience with ISDN circuits was apparently low. The procedure for ordering a circuit was cumbersome, requiring provision of extensive information regarding the equipment to be used on the circuit. The installation period was lengthy – typically it took some three to four weeks from the time of placing an order until a technician arrived to perform the installation. The competence of the installers varied greatly and Ameritech was not well equipped to test the circuits.

These factors led to difficulties in getting operational lines installed. For example, the initial three circuits were installed at ISG so that ISG could test the hardware and software. However, within a few days, the circuits no longer worked. We determined that an Ameritech technician had disconnected them at the local exchange. The reason was that no activity had been observed for several days, and so the technician took it upon himself to disconnect the circuits. We had no reason to leave hardware connected and operating on these circuits on a continuous basis, since we were only doing testing upon completion of each SmartStation. This anecdote illustrates the lack of experience at Ameritech and the negative results thereof. Even in the ordering process there were problems. We placed the order for the lines at Ingalls Memorial Hospital, for example, and then waited for installation, knowing from prior experience that the wait could be up to a month. After a month passed without installation, we called Ameritech to find out why the circuit had not yet been installed. We were told that someone had called and

cancelled the order. We, of course, had not done so. In actuality, there had been a clerical error at Ameritech – someone taking a telephone cancellation had transposed a couple of digits in the order number and our order was affected rather than the one for which the cancellation was intended. Unfortunately, Ameritech had not instituted appropriate quality control procedures for this kind of happenstance (such as a simple telephone call to us to confirm cancellation). The result was that we had to wait yet an additional month to get the circuit installed.

The necessity to coordinate line installation between Ameritech and the various site staffs greatly exacerbated the ISDN installation problems. At a few sites Ameritech did the complete installation, from their nearest exchange office directly to the room in which the equipment was to be installed. However, for most of the hospitals, an internal telecommunications group takes care of all internal wiring. Ameritech brings the lines to a "demarcation block" and the internal personnel do the wiring from that block to the final use location. At Northwestern, the internal group is an independently contracted organization called the Northwestern Technology Group (NTG). Coordinating installations between Ameritech and these internal groups added considerable time to the process, since each had schedules to keep, other responsibilities to meet, etc. NTG proved to be an incredible barrier to operations. It took literally months to get NTG to schedule the wiring to the Vanderzwicken Library. When they finally got around to performing the activity, they put the telephone jacks at the back of the library (the equipment had to be operated form the front of the room) despite explicit directions, diagrams, etc. on the order and a plea to be informed when the installation was to take place so we could have a representative on site. It then took another couple of months to get NTG to move the lines to the correct location. Months later, well into the operational phase, NTG disconnected the circuits in the course of doing some

maintenance. Again, it took weeks for restoration. Again, later in the operational phase, a billing technician at NTG noted that they were receiving no bills for those circuits (under the subcontract, ISG paid the telephone bills for all the ISDN circuits) and, without checking with anyone at the Cancer Center or ISG, blithely called Ameritech and had the lines disconnected. Again, several weeks passed before restoration.

These experiences are related not only to provide a complete report on the project activities, but also to note potential barriers that others may face in similar implementations. From the telephone company service perspective, we believe that this is an issue that has waned, if not disappeared. It was caused by inexperience at a time when ISDN circuits were fairly new and relatively rare. That is no longer the case. ISDN circuits are now quite common and Ameritech has built appropriate procedures for ordering, installation and service. For example, one has merely to note a "package type" on an order now (a single number) rather than providing exhaustive hardware descriptions. We believe that this streamlining is probably the case in other localities as well. The problems of coordination with internal telecommunications groups varied greatly from organization to organization, with NTG being by far the worst group with which we dealt in this project. We recommend that other deployers of this technology be aware of the potential logistics problems, make early contacts with the local groups, attempt to establish a relationship with a member of an internal group who will become an internal champion of the cause, and allow extra time in the preparation of the deployment schedule to allow for problems of this type.

Operation

The hardware and software systems have been operated at the seven locations since installation. The only mechanical breakdowns that have occurred have been with the

NT-1 units. These are the local devices that connect the teleconferencing hardware to the ISDN circuits. They are similar to modems, handling line balancing, termination and other electrical characteristics of the telecommunications circuits. Several of the NT-1 power supplies failed during the course of the project and one NT-1 itself failed. All failed components were replaced under warranty and none of the failures resulted in any lack of activity or loss of time.

Findings

The physicians at the remote sites notified Northwestern in advance that they wanted to include patient(s) in the next teleconference. Because the equipment budget did not permit the purchase of a TC1000 system with the multiple input sources for each of the remote sites, the pathology slides and mammography/ultrasound imagery was sent to Northwestern on the Thursday preceding each Monday conference. The patients from the remote sites were added to the agenda that was prepared each week in the Breast Cancer Center, and copies were Faxed to the remote sites a few hours before the teleconference start time. Slides and images were distributed to the Radiology and Pathology departments by that Center as well.

In practice, there were typically one to four patients from one or two remote sites presented at each conference (in addition to ten to twenty cases from Northwestern itself). Accordingly, we usually scheduled the first 10 to 20 minutes for remote site cases and then went to the Northwestern cases. The remote sites typically remained on-line after their cases were discussed, and provided input to the multidisciplinary team as well. Although the likelihood of "tapping" into the transmissions was extremely remote, only coded references were used to refer to patients (patients discussed at each conference were merely numbered sequentially and those numbers were used for

reference rather than names or Social Security Numbers or anything else that could compromise confidentiality). We established a schedule of participation for the remote sites so that cases from one or two would be included each week.

All cases, remote or local, were treated in similar fashion. The treating physician would introduce the case, the radiologist would review the imagery (mammograms and/or ultrasound images), the pathologist would review the cytology and general discussion regarding treatment would be held. Various members of the multidisciplinary team would comment as appropriate, depending upon the viable options with respect to surgery, radiology and medical oncology. In some cases, appropriate personnel commented upon a specific clinical trial or upon recent publications, as germane to the case at hand.

Though the number of cases from remote sites was relatively small (approximately 100 patients during the course of the research period) and therefore not sufficient to provide statistical data of significant power, there were indeed several instances in which the intended treatment was modified as a result of the teleconference. In the majority of cases, the multi-disciplinary team agreed with and supported the course of treatment outlined by the treating physician. This is to be expected; indeed it would be very unusual and somewhat frightening were the team to disagree with the treating physician in a majority of cases. Most of the changes in treatment were for additions to the suggested treatment, such as addition of a Tamoxifen regimen or post-operative radiation. The next most frequent change was consideration for accrual to a clinical trial. In a very few instances, the primary treatment was modified (for example, a planned radical mastectomy was replaced by a breast-conserving surgical procedure).

We believe that the observed changes in treatment are consistent with reality, are representative of the oncology discipline and are of benefit to patients. In most cases, competent physicians will choose the appropriate, state-of-the-art, optimal treatment for each of their patients. The benefit to those physicians (and their patients) that comes from participation in a multi-disciplinary conference such as this is that of the sharing of perspectives. Each specialist has some quantum of knowledge not necessarily known by all the others. That knowledge may relate to recent research studies, a long-term base of experience, close familiarity with particular clinical trials, etc. When all these specialists discuss a case, fine-tuning of the treatment plan often takes place. Seldom are there major shifts in the plan, but the participation of people with a variety of perspectives and experience often modifies the plan to some extent. In the case of the patients from the remote sites, the modifications to add some component of treatment and/or to consider a clinical trial are consistent with facts that the presenting physician from a remote site is typically a specialist (surgeon, medical oncologist or radiologist) with one perspective and that she or he is often not as heavily involved with clinical research as are those physicians at larger teaching institutions. We also believe that this model is quite representative. Many, many locales are like that in which we performed these teleconferences. There are a few, large, teaching institutions with large staffs in all the specialties and there are many smaller treatment locations with fewer staff members that do not cover the full spectrum of disciplines.

The physicians who presented their cases from the remote sites were generally pleased with the technology. Though some of the early problems with the ISDN lines were particularly frustrating, the procedure of remote participation went remarkably well once the technology was in hand. The physicians were able to present their cases as though they were physically present in the Library and, without any necessity for time-

consuming travel, were able to benefit from the discussion of their particular cases with the full multi-disciplinary team. They rated the experience as positive and beneficial to themselves and to their patients. The specialists in the Library also benefited from the input of the physicians at the remote sites, since more expertise and experience was added to the full group for each case discussed. We believe that the fact that the teleconferences could be conducted without requiring the physicians to make major modifications in their established routine was a paramount factor in its success. For the team members at Northwestern, additional cases from remote sites could be added and be treated just as the local cases were. No extensive behavioral modifications were required. For the remote physicians, they could have their cases discussed without spending two hours driving to be present at a ten-minute discussion. Again, no major behavioral modification was required to participate.

Indeed, that factor turned out to be the major determinative regarding participation of any sort. Systems were established in six hospitals, but only three participated regularly in the teleconferences. All were involved during the setup and testing, but three hospitals did not regularly present cases. In each case the reason was because to do so would have required significant behavioral modification. In one hospital (a large one), an internal multi-disciplinary breast cancer team was already in place and conducted regular scheduled meetings virtually identical to that at Northwestern. To that hospital, participation in the Northwestern Conference would have been redundant. Another hospital reviewed its breast cancer cases in a general weekly multi-disciplinary conference that covered all types of cancer cases. That conference was held very early each Monday. It did not seem appropriate for the breast cancer physicians at that hospital to repeat the activity late each Monday when they had held a meeting just that morning. In the third hospital that did not participate, the volume of cases was quite low

and the primary breast cancer physician there also practiced at Northwestern and typically attended the Multi-disciplinary Conferences in person. We expect that other locales will have similar situations and that not all hospitals in a given geographical area will necessarily participate via teleconferencing as in this study. However, the technology is appropriate for a considerable number of institutions (in our case, half the initially-defined population).

RECOMMENDATIONS

Northwestern University and the three hospitals that regularly participated during the study are continuing the teleconference participation each week. Each organization is covering its share of the expenses. It is important to note that the technology has improved significantly since the project began, and that the costs have decreased significantly in that time period as well. The TC1000 system described above is quite bulky (>1 m^2) and requires much wiring. Newer systems have completely replaced the PC with a self-contained unit that is part of the camera body. About 10% the size of the TC1000, this camera is just attached to the top of a monitor. After connecting one wire to the monitor and one telephone line to an ISDN jack, it is ready to operate. And it costs about one-third of what we paid for the TC1000. The quality of both video and audio is better than with the units we use, and it is fully compatible with VTel units and those of other manufacturers (the industry standards are not well-established). One of the hospitals, Silver Cross in Joliet, purchased one of these systems for its continuing participation in the conferences.

This study has shown that physicians can participate in multi-disciplinary conferences related to specific patients economically and efficiently. A minimal amount of time is

spent in these conferences and no time is needed for travel to attend them. The physicians benefit from the interactions with their colleagues representing a full spectrum of specialties and patients benefit from the knowledge that the full complement of participants provide. The technology is more than adequate and continues to increase in quality and decrease in cost. On this basis we recommend that other organizations adopt this technology for any areas of medical practice in which multi-disciplinary sharing of information is beneficial. Certainly appropriate are all disciplines in which major changes and advances are being made on a continuous basis – cancer is perhaps the primary example of this, but cardiology and pediatrics are among those that are similar.

Project #7 Cost-Effectiveness of Stereotactic Core Biopsy versus Surgical Excisional Biopsy for Women with Abnormal Mammograms.

PI: Charles Bennett, M.D.

INTRODUCTION:

Stereotactic core biopsy has been shown to be a useful alternative to surgical biopsy in the evaluation of nonpalpable mammographic lesions of intermediate to high suspicion.[1-3] The benefits of this procedure include less disfigurement and recovery time, lower potential for complications, and lower costs. As 60-90% of biopsies for mammographic lesions result in a benign diagnosis a less invasive procedure appears optimal.[4] Yet there is still controversy over the value of stereotactic core biopsy in highly suspicious lesions or lesions of certain types (clusters of calcifications).[5] Some believe that in lesions likely to be cancer or those a core biopsy is more likely to miss, the core biopsy adds an additional procedure and is not a benefit to the patient or cost-effective.

The purpose of this study is to evaluate and compare the cost-effectiveness of these procedures, from the time of biopsy through definitive surgical treatment. A decision analytic model of the outcomes of all biopsy patients seen at the Lynn Sage Breast Center during a two year period will be stratified by suspicion, mammographic lesion and definitive surgery and used to determine the total costs.

BODY:

Methods

A decision analysis model was formulated to represent the flow of decisions and chance events related to the consequences of an abnormal mammogram, as practiced in our institution. These assumptions were utilized to develop a decision tree which was used to perform the cost analysis.

The two main branches of the tree, core biopsy or surgical biopsy, have the possibility of four diagnoses: invasive cancer, ductal carcinoma in situ, benign, or missed. Missed diagnoses will be classified as those DCIS or invasive cancer diagnoses determined either via a second biopsy procedure within one month (technical miss) or by a biopsy procedure resulting from a suspicious mammogram within one year of a benign diagnosis.

The third tier of the tree represents the treatment possibilities for each diagnosis. For invasive cancer they are mastectomy or lumpectomy (with or without lymph node dissection). Patients receiving a lumpectomy will have tumor margins evaluated as negative or positive. The lumpectomy is definitive when the margins are negative, or further re-excision or mastectomy is performed when the margins are positive. Patients with a diagnosis of DCIS under go either a re-excision or mastectomy without lymph nodes. Patients with confirmed DCIS and negative margins require no further surgery. Those patients whose disease is determined to be invasive will have axillary node dissection, and if the biopsy margins were positive, re-excision or mastectomy. Benign patients are followed for follow-up mammogram results at 6 months and one year post biopsy.

Information was collected on all patients seen at the Lynn Sage Breast Center for a surgical or core biopsy from September 1, 1996 through August 31, 1998. A monthly printout of each patients age, biopsy procedure, lesion type, degree of suspicion, and pathological diagnosis was prepared from the Breast Center's MRS database. Missing data were provided via chart review. Follow-up information on surgery performed was obtained from the Northwestern Memorial Hospital Pathology Department. This information was also used to verify biopsy-related data. The data were combined into a database that was reviewed by Drs. Venta and Morrow for clinical relevancy. These clinical data were used to define the probabilities for each node of the decision tree.

Patient billing records were collected for randomly selected patients from each definitive arm of the decision tree and a mean cost per procedure was determined. Resources utilized were reviewed by Drs. Venta and Morrow to assure that patients selected were representative of typical diagnostic and treatment procedures. The mean costs were applied to the probability of each procedure and a total cost per biopsy type computed.

Results to Date

Clinical data have been collected on all patients for the two year time period, September 96-August 98. A total of 1307 core biopsies were performed on 1121 patients, and 545 surgical biopsies on 501 patients. The mean age of the patients was 53 years in the core biopsy group and 55 years in the surgical biopsy group.(Table 1) There was a higher percentage of calcifications biopsied in the surgical group (52% vs 40%) and a higher percentage of masses biopsied in the core group (55% vs 39%). Lesions diagnosed via core biopsy had a higher distribution of suspicion rated at 2-3, and those diagnosed with surgical biopsy had a higher distribution rated at 3-4. Of surgical biopsied lesions, 26.1% were diagnosed as cancer (DCIS or invasive), and of core biopsied lesions, 20.4%. (Table 1)

Overall, 80.9% of surgical biopsy versus 73.9% of core biopsy lesions had a single procedure for diagnosis and/or therapy ($p<0.001$). Of those lesions diagnosed as cancer, only 33% of surgical biopsied underwent a single surgical procedure, in comparison to 84.2% of core biopsied ($p<0.001$).(Table 2) These differences remained significant, in favor of core biopsy, when stratified by suspicion grade or lesion type. In comparisons of definitive surgery, those lesions resulting in mastectomy and lumpectomy plus lymph nodes were also more likely to be treated by one surgical procedure in the core biopsy versus surgical biopsy group (Table 2). But for lesions

treated with breast conserving surgery (lumpectomy only), there was no difference between biopsy groups of the percentage of lesions requiring only one surgical procedure (69.7% of surgical biopsied lesions had a single procedure compared to 75.3% of core biopsied, p=0.45). Core biopsied lesions were more likely to require additional surgery after an attempt at definitive local therapy was completed, 15.7% for core biopsy versus 2.1% for surgical biopsy (p=<0.001).

The probabilities determined above were applied to the decision trees. The final versions of the trees are attached as Figures 1 and 2. Mean costs have been determined for each terminal branch and used in the decision analytic model of costs. The total direct medical cost of each biopsy procedure, from the date of biopsy through definitive surgery, was calculated by multiplying the total cost of each branch of treatment by the clinical probability of its outcome and summing these values. The total costs of diagnosis and surgical treatment was $1,879 for core biopsy versus $2761 for surgical biopsy. The total costs for patients diagnosed with cancer (either DCIS or invasive) was $5,857 for core biopsy versus $5,055 for surgical biopsy. For patients treated with breast conserving surgery (lumpectomy only) total costs were $3,587 for core biopsy and $2,786 for surgical biopsy.

Future work will include estimates of significance, univariate sensitivity analyses, and Monte Carlo analyses of the cost values to determine the robustness of the estimates. This will involve collecting a larger set of patient billing data for each of the procedures. Follow-up of benign lesions will be conducted to determine the number of incorrect diagnoses in each group and to calculate the sensitivity and specificity of these procedures. These values will be factored into the cost estimates if they differ significantly.

KEY RESEARCH ACCOMPLISHMENTS:

- Developed a database of all consecutive patients seen for a breast biopsy at a single center for a two-year time frame. The database contains information on patient age, mammographic lesion type, grade of suspicion, type and date of biopsy, pathologic diagnosis, margin status, and follow-up surgery.
- Devised a decision analytic model representing the flow of diagnostic and treatment decisions at this center.
- Determined that for cancerous lesions (overall), lesions diagnosed by core biopsy are more likely to require only one surgical procedure than those diagnosed by surgical biopsy. This difference holds when data are stratified by lesion type, lesion suspicion, or definitive surgery.
- Determined that for cancerous lesions treated by a lumpectomy only, the percentage of patients treated with a single surgical procedure is equivalent for both types of biopsies.
- Estimated that the total direct medical costs (from the date of biopsy through definitive surgery) for core biopsy was less than for surgical biopsy, overall
- Estimated that the total direct medical costs for lesions diagnosed as cancerous, and those treated with breast-conserving surgery (lumpectomy only) were lower for patients diagnosed with a surgical biopsy.

REPORTABLE OUTCOMES:

Morrow M, Venta LA, Stinson T, et.al. Is core biopsy the diagnostic procedure of choice for all mammographic abnormalities? American Society of Clinical Oncology, Atlanta GA, May 1999, Poster Presentation Proc Am Soc Clin Oncol 1999;18:Abstract 299.

CONCLUSIONS:

To date, we have determined that overall, lesions diagnosed as cancer by core biopsy are more likely to require a single surgical procedure than those diagnosed by surgical biopsy, 84.2% versus 33%, p=<.001. Consequently, lower total costs (from biopsy through definitive surgery) were noted for the core biopsy group. These values are consistent with the current literature. Reports comparing total costs of these biopsy procedures have determined cost savings of $740- $1000/patient.[5-9] In the subset of lesions treated with breast conserving surgery (lumpectomy only) the proportion of lesions requiring only one surgery was equal, 69.7% for surgical biopsy and 75.3% for core biopsy (p=0.45). This translated to a $801 savings for the surgical biopsy group. While core biopsy may be cost-effective overall, there are cost benefits to surgical biopsy in lesions diagnosed as cancerous when utilizing breast conserving surgery without axillary dissection. Surgical biopsy may be the procedure of choice for highly suspicious calcifications suitable for breast conserving surgery.

Table 1. Descriptive Statistics of Data Set

	Surgical Biopsy	Core Biopsy	P value
# Patients	501	1121	
# Lesions	545	1307	
Mean Age	55.2	52.7	0.0004*
By Lesion			
Lesion			<.0001**
Arch Distort	48 (8.8%)	65 (5.0%)	
Calcs	284 (52.1%)	521 (39.9%)	
Mass	213 (39.1%)	721 (55.1%)	
Suspicion			<.0001**
1	73 (13.4%)	190 (14.5%)	
2	139 (25.5%)	488 (37.3%)	
3	189 (34.7%)	410 (31.4%)	
4	109 (20.0%)	136 (10.4%)	
5	35 (6.4%)	83 (6.4%)	
Diagnosis			<0.01**
Benign	403 (73.9%)	1040 (79.6%)	
Cancer	142 (26.1%)	267 (20.4%)	

*Two-tailed t-test, a=.05
**Two-tailed chi square test, a=.05

Table 2. Percent Lesions Treated with a One-Stage Surgical Procedure.

	Surgical Biopsy	Core Biopsy	p Value
All Cancers	33.0%	84.2%	<0.001
Mastectomy	0.0%	88.2%	<0.001
Lumpectomy + LN	46.5%	84.5%	0.001
Lumpectomy Only	69.7%	75.3%	0.45
By Suspicion 1-3 4-5	 35.7% 30.6%	 83.8% 84.6%	 <.001 <.001
By Lesion Masses Calcifications	 25.6% 42.2%	 81.7% 89.1%	 <.001 <.001

Two-tailed chi square test, a=.05.

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PROJECT #8

INPATIENT VERSUS OUTPATIENT HIGH-DOSE THERAPY

JANE WINTER, MD, PRINCIPAL INVESTIGATOR

INTRODUCTION

The cost of high dose therapy with stem cell rescue for the treatment of malignant disease has escalated over recent years, ranging from $50,000 to $103,000 (1), and the numbers of patients seeking such therapy nationally has grown exponentially. Recent concerns over health care costs have led to increasing interest in outpatient transplant. The use of growth factors and peripheral blood progenitor cells has made outpatient transplant a possibility. Early reports have demonstrated reductions in the length of hospital stay without compromising short-term outcomes (2-4). Although there is the perception that outpatient therapy is less expensive than inpatient treatment, this has yet to be fully considered. Meisenberg et al showed a reduction in costs from $39,700 for inpatient treatment to $29,400 for outpatient treatment (from first day of chemotherapy to 30 days post transplant) (5). This study measured only the direct medical costs, or cost to the third party payor. When one considers the efforts and resources required by the patient and the round-the-clock caregiver for an outpatient transplant, it is possible that a considerable portion of the total costs were excluded. Another argument used to justify outpatient transplant over the traditional inpatient stay is the perception that outpatient therapy results in a superior quality of life (QOL) for patients, but this has not been studied.

Jagannath et al compared the costs of inpatient and outpatient transplant for multiple myeloma treated with high-dose melphalan.(6) Their analysis included a blanket

estimate of caregiver costs of $100 per day. They determined significantly lower charges for outpatient transplants, $37,403 compared to $50,575, resulting from savings in hospitalization, pharmacy and laboratory costs, but their estimates of caregiver costs may be substantially under valued. Results from the National Hospice Study (an evaluation of the costs and quality of care for terminal cancer patients) measured the opportunity costs (the value of their lost wages or productivity) for each of the caregivers in their study.(7) They determined that 60% reported a loss of income because of care-related time missed from work, which averaged $2582.

The purpose of this project is to investigate and compare the societal costs (direct medical, indirect medical and indirect personal) of outpatient versus inpatient autologous transplant for a prospective, case-matched cohort of patients with breast and hematologic malignancies. Also, quality of life assessment and comparison of inpatient and outpatient quality of life will be analyzed both descriptively and quantitatively to determine if outpatient transplant is associated with an enhanced quality of life.

WORK TO DATE

Patient Accrual

Every new transplant candidate evaluated by the Northwestern University/Northwestern Memorial Hospital stem cell transplant program is screened for eligibility by the program research coordinator (P. Frey, RN) who discusses the option of participation with each patient individually. Additionally, each patient is discussed as a possible candidate for outpatient bone marrow transplant at the weekly bone marrow transplant team meeting. If patients are interested in pursuing outpatient transplant, the coordinator works closely with them to find a suitable caregiver. The research coordinator/nurse continues to be

involved in educating insurance companies and case managers about the outpatient transplant process.

As of July 27, 1999, 136 individuals have been screened. Table 1 gives the percentages and reasons why patients were unable to have an outpatient transplant.

This data was submitted and published in abstract form at the American Society of Hematology Meeting in December, 1998. Updated data on lack of utilization of outpatient stem cell transplant was submitted and presented at a general poster session at the American Society of Clinical Oncology Annual Meeting in May, 1999. Despite the potential for cost saving and possible improvement in quality of life, it is noted that outpatient transplant is applicable to fewer than half of all transplant patients. Table 2 shows the various reasons that patients do not have an available caregiver. Also, after psychosocial evaluation by our psychiatry consult service, six patients and prospective caregivers (4.4%) were excluded from participating in outpatient transplant because of significant psychosocial issues. This emphasizes the importance of formal psychosocial screening for both patients and caregivers.

A total of 41 patients have been enrolled on this study. Twenty of these have been outpatients and twenty one have been inpatient controls. The disease site breakdown is demonstrated in Table 3. Further descriptive statistics for the patients enrolled on the study are shown in Table 4.

The total number of autologous stem cell transplants done at our institution in the last year has decreased attributable to a decline in breast and multiple myeloma transplants making accrual more difficult. The release of the randomized phase III autotransplant

trial results for patients with breast cancer is felt to be largely responsible for this. Also, at our institution, there has been a switch to allogeneic stem cells instead of autologous as the preferred source for patients with multiple myeloma. Allogeneic transplant patients are not eligible for outpatient transplant.

Quality of Life

Quality of life instruments are administered verbally by the research coordinator/nurse to all patients and to caregivers of outpatients on a weekly basis beginning just prior to high dose chemotherapy and continuing for one month post-discharge. Data is complete on 41 patients. One patient is not yet one month after discharge. The research coordinator/nurse is responsible for scoring the quality of life instruments and assists in entering the data into the data base. An SPSS data base has been established to collect quality of life data. A case report form is used to compile necessary information. Data is entered into the data base by two people to help insure accuracy. Analysis is in progress.

Cost Comparison

Clinical information for each enrolled patient was obtained from specifically designed case report forms, including dates of procedures, age, sex, disease and stage, treatment regimen, hospitalization and use of supportive care agents. Detailed financial records were obtained from the following sources: inpatient records included hospital bills and physician consult bills, outpatient records included home health bills, hospital bills (which include outpatient pharmacy charges and fees for the use of the outpatient cancer treatment facility), and physician consult bills. Data were collected from the beginning of high-dose therapy through discharge from the appropriate facility. Charges related to stem cell harvest and pre-transplant evaluations were excluded. Case report forms were

used to cross-check the financial records and determine possible missing information. The transplant nurse and Principal Investigator reviewed cost summaries for accuracy and completeness. Outpatients were housed in a Northwestern Memorial Hospital owned dormitory facility at a rate of $100/day.

All outpatients and their caregivers were asked to complete a diary during their stay that collected information on out of pocket costs for medical care and meals, indirect costs due to the patients or caregivers absence from home (babysitting, home cleaning, lawn mowing, etc.), insurance deductibles, and time from work (paid or unpaid). The total out of pocket costs to the patient and caregiver were calculated. To quantify the costs of the caregivers time we evaluated their "opportunity costs". Measuring opportunity costs involves equating the cost of using ones time in a given activity (such as caregiving) with the opportunities forgone (usually working) to perform this activity. This value is typically approximated using the individual's labor market earning per time unit.(7,8) The average daily income for each caregiver was estimated from their stated occupation and US Bureau of Labor statistics for the Chicago area. For caregivers that were retired, we used the average hourly wage of a Chicago area employed person, $16.86. The estimated daily wage was multiplied by the number of days spent with the patient in the outpatient facility.

RESULTS

Quality of Life/Caregiver Availability

We are continuing to collect data on caregiver availability as well as the other reasons that patients are unable to proceed to outpatient stem cell transplant. Also, the impact of a formal psychosocial screening for both patients and caregivers is being evaluated to

see what impact this has on caregiver availability. We are beginning to analyze the quality of life and caregiver information for the two arms.

Cost Analysis

Preliminary data analyses have been completed for the first twelve inpatients and thirteen outpatients. The patients were approximately the same age in both groups (50 years) and there were no male patients in the inpatient group. The inpatient group had a higher proportion of breast cancer patients, whereas the outpatient group had more multiple myeloma patients. Basic demographic information was also collected from the caregivers. 10/13 caregivers completed the diaries and questionnaires. Table 5 describes their characteristics. They averaged 54 years of age and were equally divided between men and women. Most caregivers were spouses of the patient, with a high level of education and income, and were employed full-time. Three of the caregivers took unpaid leave to assist the patient, four used sick or personal time and three were retired. Caregivers spent an average of 1.56 hours per day providing medically-related care for the patient.

Treatment charges for each patient were received from the beginning of high-dose therapy through discharge. Charges were converted to costs using the hospital department specific cost to charge ratios. Home Health charges were converted using the Medicare cost to charge ratio for the appropriate year of service. Charges for physician fees and nursing costs did not have a cost to charge ratio, so they served as a proxy for costs. The total cost of treatment for inpatients included only direct medical costs. For outpatients total costs included direct medical costs, out of pocket costs to the patient and caregiver and the opportunity costs of the caregiver. The median inpatient total length of stay was 19 days, compared to 17 days total stay for outpatients.

Outpatients had a median hospital stay of 3 days and outpatient facility stay of 12 days. The total costs of outpatient treatment were significantly lower than inpatient treatment, a $10,379 difference, p=.019 (Table 6). Outpatients had significantly lower costs in specific departments, such as room costs, pharmacy, physician fees, and labs. Costs incurred by outpatients not seen in the inpatient categories were for home health nursing and for caregiver costs. Out of pocket costs and caregiver opportunity costs accounted for 7.6% of the total costs for outpatients.

KEY RESEARCH ACCOMPLISHMENTS

- Developed a database that contains clinical, demographic and economic information on a case-matched cohort of autologous transplant patients
- Characterized outpatient caregivers and devised methodology to evaluate indirect costs in the transplant setting
- Estimated the total costs of treatment for inpatient and outpatient transplants, including hospital, physician, home health, out of pocket and caregiver opportunity costs. Provided a breakdown of these costs by department.

REPORTABLE OUTCOMES

Portions of the above data was presented as in abstract form at the 1998 American Society of Hematology Meeting and also as a poster presentation at the 1999 American Society of Clinical Oncology Meeting in May of this year. A copy of the abstracts are attached as Appendices 1 and 2.

CONCLUSIONS

There are significant savings to performing outpatient autologous transplant. The total costs of outpatient transplant are $10,379 less than inpatient transplant. Significant savings in costs are seen in room costs, pharmacy, physician fees and labs. Indirect costs, including out of pocket costs and caregiver opportunity costs, account for 7.6% of the total costs of transplant. Despite this savings, outpatient transplant is applicable to fewer than half of all transplant patients. The shift in caretaking responsibility from hospital to the patients' friends and family resulting from outpatient transplant is the main reason.

FUTURE DIRECTIONS

Accrual to this study continues in an attempt to reach the original accrual goal over the next year. Based on the information we have collected on lack of available caregivers, as well as the formal psychosocial screening of caregivers, we are assembling and analyzing the data collected and preparing to submit it for publication.

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TABLES

Table 1 Patients Screened for Outpatient Transplant

	Number (%) Total N = 136
Proceeded to outpatient bone marrow transplant	20 (14.7)
Did not have transplant at institution (went elsewhere, disease progression, decided against transplant)	27 (19.9)
No caregiver available	60 (44.1)
Medical or psychosocial issues	11 (8.1)
Insurance issues	13 (9.6)
Refused and no reason given	5 (3.6)

Table 2 Reasons for Lack of Caregiver

	Number (%) Total n = 60
Single or widowed patient with no identifiable caregiver	**26 (43.3)**
Caregiver needed for care of children	**27 (31.7)**
Caregiver unavailable because of need to work	**14 (23.3)**
Caregiver responsible responsible for sick family care	**1 (1.7)**

Table 3 Patient Diagnoses

DISEASE	INPATIENT N (%)	OUTPATIENT N (%)
Breast Cancer	12 (57.1)	6 (30.0)
Lymphoma (Hodgkin's and non Hodgkin's)	5 (23.8)	5 (25.0)
Multiple Myeloma	4 (19.0)	9 (45.0)

Table 4 Patient Characteristics

DESCRIPTION	INPATIENT	OUTPATIENT
Sex		
Male/Female	**4/17**	**6/14**
Age (years)		
Mean(Range)	**49(24 – 70)**	**50 (28 – 64)**
Total length of stay Mean(Range)	**20.9 (17 – 31)**	**17.2 (14 – 22)**
Number of inpatient days		
Mean(Range)	**20.9 (17 – 31)**	**4.1 (0 – 17)**
Caregiver types Number(%)		
Parent	**n/a**	**3 (15)**
Extended family	**n/a**	**5 (25)**
Spouse	**n/a**	**8 (40)**
Children	**n/a**	**4 (20)**

Table 5 Outpatient Caregiver Characteristics

Mean Age **(Range)**	**54.5 years** **(31-66)**
Gender **Male** **Female**	 **5** **5**
Relationship to Patient **Spouse** **Parent** **Child** **Other Relative**	 **5** **2** **1** **2**
Education **High School** **Some College** **College Degree** **Advanced Degree**	 **3** **1** **2** **4**
Household Income **$20,000-$50,000** **$50,000-$80,000** **>$80,000**	 **4** **1** **5**
Employment Status **Full Time** **Part Time** **Retired**	 **5** **2** **3**
Leave Taken **Sick Leave/Personal Days** **Unpaid Leave** **Retired**	 **4** **3** **3**
Mean Total Hours Spent Providing Medically- Related Care to Patient **Mean Hours per Day**	**19** **1.56**

Table 6 Total Median Costs of Treatment

	Inpatient (n=12)	Outpatient (n=13)	p Value
Room	14,094	6,417	<.001
Pharmacy	15,933	11,587	.019
Physician Fees	4,637	2,754	<.001
Nursing	---	2,597	
Lab	3,155	1,802	.001
Blood Products	3,565	2,162	.082
Radiology	459	207	.102
Caregiver Costs	---	2,767	
Other	2,737	2,018	<.001
Total	$46,731	$36,352	.019

Appendices Project 2

Appendix 1

1. Chicago Ethnic Communities Breast Cancer Education Project Personal Information Form
2. Chicago Ethnic Communities Breast Cancer Education Project Mammogram Questionnaire
3. Chicago Ethnic Communities Breast Cancer Education Project Mammogram Questionnaire (current version)
4. Chicago Ethnic Communities Breast Cancer Education Project Breast Cancer Facts

Appendix 2

1. Chicago Ethnic Communities Breast Cancer Education Project Sample: Staff Meeting Summary reports

Appendix 3

1. Consultant's report on PE retention

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
PERSONAL INFORMATION FORM

1. Name _____ Date of Birth/Age_____

2. Number of Children_____ Marital Status: Married ____
   Single ____
   Widowed ____
   Divorced/Separated ____

3. Country of Origin _____ Years of School Completed _____

4. Preferred Language_____

5. Do you speak English? Fluent_____ Some_____ Very Little_____

   Do you read English? Fluent_____ Some_____ Very Little_____

6. What other languages do you speak or read? _____

7. Do you work outside the home? Yes_____ No _____

8. How long have you lived in the USA? _____

9. Do you have health insurance? Yes_____ No_____ (Pay Cash)

   Indicate which kind: Private_____ Medicare_____ Medicaid_____

10. Do you have a doctor or clinic you go to regularly? Yes_____ No_____

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
MAMMOGRAPHY QUESTIONNAIRE

NAME_____ **AGENCY**_____ **DATE**_____

Pre Test_____ **Post Test**_____

5=Strongly Agree or always	**4=Agree or Sometimes**	**3=Neither Agree or Disagree Neutral**	**2=Disagree or Rarely**	**1=Strongly Disagree or Never**

1.	If I eat a healthy diet, I will lower my cancer risk enough that I probably do not need to have a mammogram	5	4	3	2	1
4.	I would probably not have a mammogram unless I had some breast symptoms or discomfort.	5	4	3	2	1
6.	Once you have a normal mammogram, you don't need to have any more mammograms.	5	4	3	2	1
8.	I would be more likely to obtain a mammogram if a doctor told me how important it was.	5	4	3	2	1
11.	Mammograms are now a very common medical test.	5	4	3	2	1
12.	My family will benefit if I have a mammogram.	5	4	3	2	1

Rev: 8/14/97

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
HEALTH BELIEF QUESTIONNAIRE

Name _____ **Agency** _____ **Date** _____

Pre test _____ **Post test** _____

5=Strongly Agree or Always	**4=Agree or Sometimes**	**3=Neither Agree or Disagree Neutral**	**2=Disagree**		**1=Strongly Disagree Rarely or Never**	
4. There is a high possibility that I will get breast cancer.			5	4	3	2	1
7. The thought of breast cancer scares me.			5	4	3	2	1
9. If I had breast cancer my daily home activities or career would be endangered.			5	4	3	2	1
18. If I had breast cancer, my whole life would change.			5	4	3	2	1
20. I have a lot to gain by doing self breast exams.			5	4	3	2	1
22. If I do monthly breast exams I may find a lump before it is discovered by regular health exams.			5	4	3	2	1
23. I would not be so anxious about breast cancer if I did monthly exams.			5	4	3	2	1
33. I always follow medical orders because I believe they will benefit my state of health.			5	4	3	2	1

REV. 8/14/97

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
BREAST CANCER FACTS

Name:_____ **Agency**_____ **Date**_____

Pre test_____ **Post test**_____

READ OR LISTEN TO EACH STATEMENT. IF SOMEONE YOU KNOW SAID THIS TO YOU, WOULD YOU THINK , "YES, I AGREE, THIS COULD BE TRUE"; OR WOULD YOU THINK "NO, I DISAGREE. I DON'T THINK THIS IS TRUE". IF YOU AGREE WITH THE FOLLOWING STATEMENTS, WRITE A LARGE "Y" NEXT TO THE LINE. IF YOU DO NOT AGREE, WRITE A LARGE "N" NEXT TO THE LINE.

1. Breast cancer is the most common cancer in women. _____
2. Doctors know what causes breast cancer. _____
3. If no one in my family ever had breast cancer, then I cannot get it. _____
4. Breast pain is a sign of breast cancer. _____
5. Breast cancer is more likely to happen to old women than to young women. _____
6. Breast cancer is contagious. _____
7. Breast cancer can be cured. _____
8. Old women SHOULD have mammograms. _____
9. The best way for me to find a lump that might be cancer is to do breast self exam, have a doctor or nurse examine me and get a mammogram. _____

10. AT WHAT AGE SHOULD MOST WOMEN GET A MAMMOGRAM FOR THE FIRST TIME?

_____20 _____30 _____40 _____50 _____60

11. HOW OFTEN SHOULD YOU DO A BREAST SELF EXAM?

_____Once a WEEK _____Once a MONTH _____Once a YEAR

12. HOW OFTEN SHOULD YOUR DOCTOR CHECK YOU FOR BREAST LUMPS?

_____Once a MONTH _____Twice a YEAR _____Once a YEAR

15. WOMEN WHO ARE OLDER THAN 50 SHOULD GET A MAMMOGRAM

_____Every 6 MONTHS _____Every YEAR _____Every 2 YEARS _____ Every 5 YEARS

THANK YOU FOR TAKING OUR BREAST FACTS QUIZ.

REV. 8/14/97

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
STAFF MEETING SUMMARY
June 10, 1999

Present: Florence Dunham, Agnes Chen, Rachita Singh, Zumra Kunosic, Janet Kim, Selam Azmera, Saffiya Shillo, Miriam Rodin, Ginny Warren

I. Welcome and Introductions

This month we welcomed two new members to the project: **Janet Kim from Korean American Community Services**, and **Saffiya Shillo from the Arab American Action Network**. Following the staff meeting they received training as community health advocates for the breast cancer project.

II. Articles Review

Two articles were handed out, and briefly discussed by Dr. Rodin. The first, ***A Study Plays Down Estrogen Link to Breast Cancers***, describes a recent study at NU that finds little evidence linking hormone replacement therapy (HRT) with the most common forms of breast cancer (ductal or lobular). Still of concern however, is the finding that HRT increases risk of less common breast tumors (tubular, medullary, papillary, mucinous). The good news is that the less common tumors are easier to cure.

Often women who are most at risk for breast cancer (those, with a strong family history) are least likely to take advantage of mammography screening. The second article: ***....A Trial of Breast Cancer Risk Counseling: The Impact on Mammography Use*** describes a study looking at individualized risk counselling for women who have a close relative with breast cancer. The assumption is that women will get mammograms if they fully understand their risk. The study's findings, however, suggest that risk counseling may in fact be counter-productive. Among women with less education, the rate of screening actually decreased. For those with more education, the rate of screening stayed the same.

This article has some implications for our project. The writers reported that initially there was no difference in mammography rates between more and less educated women. The women with less education, however, had overestimated their chances of getting breast cancer. After individual risk counselling with a professional health educator, these women were reassured to know they were less likely to breast cancer than they had thought, and were, therefore, less motivated to get mammograms.

This shows us that information is not all the same or understood the same. Sometimes statistics can confuse, or convey the wrong message....particularly with those who have had little education. Our task is to promote women's confidence in looking after their own health, particularly in getting mammograms, and seeing that their doctors examine them and refer them appropriately. We want women to understand that breast cancer is not common, but can be very serious if not detected early; and if detected early there is

effective treatment that will permit them to go on with their lives, working and caring for their families.

Also since our staff meeting, another issue of **JAMA** has come out with a report on the effects of *raloxifene (tradename Evista),* an estrogen-like drug that is primarily used to treat or prevent osteoporosis. It is very similar *to tamoxifen (tradename Novadex*) which has been used to treat breast cancer and which was recently tested for prevention of breast cancer. **Tamoxifen was about 50% effective in preventing breast cancer in high risk women. Raloxifene was about 75% percent effective.** But it was a small study, comparatively speaking, and the real benefit could be smaller. In any case, don't all run out and get raloxifene. All medicines have risks as well as benefits. You need to know if the risks outweigh the benefits TO YOU.

III. Problem-solving session with Agnes concerned a 33 year old Chinese woman who speaks no English and is uninsured. 2 months ago, she noticed a lump in her R breast. She asked her doctor about this. The doctor said it was nothing to worry about and that there was no need for a mammogram, however, she is still very worried. She cannot get a screening mammogram without a doctor's order because she is too young, and can't afford to pay for another doctor's visit.

The nearest Chicago Department of Health Clinic, Lower West, will evaluate her *if she brings in her own interpreter.* By law every hospital and clinic must provide interpreters for anyone not speaking English.

There are actually 2 problems here:

#1 Agnes' client needs a medical evaluation for a breast lump. Where can she go that she can afford?

#2. Should Agnes or CASL file a complaint against the CDPH clinic for refusing to provide an interpreter for her non-English speaking client? And if so, with whom?

Solution to problem #1 (generated by Agnes and Ginny)

Cook County Hospital Breast Clinic provides clinical breast exams done by RNs and screening mammograms by appointment. For women without insurance, fees are determined by sliding scale depending on income. Interpreters are provided at time of arrival.

Phone: 312- 633- 5471, Contact Loretta for appointments

Women with a breast lump should go to the **CCH Breast Oncology Clinic** for evaluation by a specialist. **Phone: 312- 633- 8836**

Solutions to problem #2 (generated by the group)

Option 1: Call or write to Bill Card, describing the problem you had with Lower West about providing interpretation services to this Chinese woman. Mr. Card is Assistant

Commissioner for CDPH Community Clinics and he is very interested in providing good care to all communities.

Option 2: Mail letter of complaint with all details to Pat Lucas of the Office of Civil Rights, DHHS, which will follow up with the CDPH for you.

Option 3: Contact Karin Rueschke with the Interpreters Service of Heartland Alliance who also will personally help you with this problem.
Phone is 773-271-1073.

IV. By our next meeting, July 8, all 1998-99 info must be in. This includes all outstanding logs, F/Us, # women getting mammograms, and any abnormal mammograms, biopsies, ultra sounds, etc, that you know of. This is necessary because the annual report to the Army is due and Dr. Rodin needs time to analyze it and write up.

V. Our **annual summer party in honor of the PHEs** is set for Thursday, August 5, from 5 to 7PM, at the new Bosnian Center (BHACC) on north Sheridan Road. Dr. Rodin suggested we have an ice cream social this year instead of the usual potluck.....with lots of fruit. Great idea?!?

VI. Next Staff Meeting will be Thursday, July 8,10-12, at our Northwestern office again, Buehler Center, Suite 601, 750 N. Lake Shore Drive.

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
JULY STAFF MEETING SUMMARY

Buehler Center on Aging

July 8, 1999

PRESENT: Agnes Chen, Janet Kim, Mela Smith, Florence Dunham, Ginny, Dr. Rodin
ABSENT: Selam Azmera, Zumra Kunosic, Rachita Singh, Saffiya Shillo

We missed those of you who were not here for the meeting Thursday. You missed Dr. Rodin's exhortation re: what she needs from you to complete our project's 98-99 annual report, due August 1. As you have heard *ad nauseum*, the most important element of this year's research is FOLLOW-UP, soooo.... **if you have any additional follow-up info on women from your community, please get it to Ginny ASAP** so she can enter it in the data base. In addition, we need to know **how many ladies had mammograms this project year,** .....dates, names and ages are helpful so I can correlate them with your logs. **This info must be in by Thursday of this week!!!**

Agnes gave us a brief report on the status of her client who found a lump in her breast after learning to do BSE. She went to Mercy Hospital for her mammogram; following the mammogram, she had surgery of some kind. Agnes is not sure just what was done since she has been unable to contact the woman. A copy of last month's summary with Agnes' report was sent to Bill Card at CDPH. He responded immediately, and so did the director of Lower West clinic, with assurances that every effort would be made to provide interpreters upon request in the future.

We briefly discussed the upcoming PHE event scheduled for Thursday, Aug 5.....an ice cream social at the new Bosnian Community Center on north Sheridan, from 5:30-7:30 PM. Let your PHEs and agency directors know, and all are welcome to bring family members too. I will be calling you soon for names and addresses.

Announcements:
*The new Bosnian center is having an **Open House on Thurs, July 15 form 4P- 9PM,** the new address is 6574 N. Sheridan. They have a great new center just half a block north of the Loyola El stop.
* Selam's baby is due this week!!!
*The Arab American Action Network is completing PHE training Friday, July 9.
*The Korean American Community Center begins their PHE training Mon, July 12 and Janet Kim has the new coordinator of senior services for their two Korean Senior Centers.

The next time we are all together will be at the party Aug 5.....
Keep cool!!!

August 21, 1998

I enjoyed the group very much and feel that among the group there is rich knowledge and insight. It takes a long time to really process and we seem to have only just begun. I am enclosing some impressions...these are preliminary and with more time the group can develop recommendations based on what works in order to improve the program, build on its strengths, etc.

1. The group of advocates is very motivated and committed to this project. You Miriam and Ginny have done an excellent job of recruiting your partners. Where the PHEs don't always produce, the advocates step in. (That may or may not be what you want, but it does show commitment.) I sense that Florence is the most frustrated and discouraged, worries that your funding to her agency will be reduced or cut. This needs to be addressed.

The group is incredibly diverse and supportive of each other. I can imagine other projects branching off from this. I'm really impressed with how much knowledge the group has collectively....also how the project works differently within different communities. Describing how the differences are manifesting would be meaningful to write up.

2. *Recruitment and Retention of PHEs*

More attention can be paid to recruitment criteria. Selecting fewer may yield greater success. There my be pressure to produce the numbers which can result in recruiting out of pressure, not necessarily the most appropriate people. On the other hand realizing the attrition rate is a normal expectation takes pressure off the advocates and yourselves. If you build that in and recruit several times during the year, there are benefits to having recruited and trained a number of PHE's even if they don't remain active. You have to considerthat these PHEs are still influencing others over time, indirectly, not in a measurable way, but still having a positive role in their communities.

3. Some useful recommendations that emerged:

*Work on simplifying terms
*Consider increasing CHA time commitment from 10 hours
*Additional training for PHEs: anticipate kinds of questions they will be asked so that training can include them, or spend time role playing how to deal various questions
*Develop future job opportunities, career paths, education for PHEs...perhaps levels so that those who sustain involvement can have increasing responsibility, leadership, dollars, incentive.

Hope this is helpful. I really enjoyed the experience.

Best,

Peg Dublin
917 Madison St
Evanston,. IL 60202
W: 312 413 0068
H: 847 864 6528

Staff Meeting Summary
Bosnian Refugee Center
June 24, 1998

Guest: Peg Dublin, RN
Director Chicago Health Corps

Present: Rachita Singh, Selam Asmera, T.J. Gatwood, Zumra Kunosic, Young Klessig, Jung Sook Yoo, Florence Dunham, Mei Leng Chong, Lucy Le Kissane, Ginny, Dr. Rodin

Hi folks

Time is flying, I can't believe it's only a week until the next staff meeting and little more 'til our year' end celebration honoring the Peer Health Educators. Enclosed are flyers for you to give to the PHEs with date, time and place. We have reserved the reception room on the 1st floor of the bank building at Lawrence and Broadway. You can take a look at it when we gather at Asian Human Services for the next staff meeting.

Please call and and let me know how many from your agency will be attending the party (all I hope). The 4 Mutual Aid Associations will be joining us too. Since it is a potluck please bring a dish to share. My estimate is that we will have 40-50 people attending. Mimi and I will provide drinks, plates, cups, bread, fruit and vege platters similar to last year.

Following are my notes from our last staff meeting. Please refresh your memories by reading through this, and come to the next staff meeting prepared to continue our discussion. Peg will be back to facilitate.

Responding to your often voiced concerns about PHE motivation, team building and leadership, we invited Peg Dublin to join us to work on these issues. She has worked with PHEs for over 10 years, first with the Breast Feeding Task Force at Cook County Hospital, and presently with the Chicago Health Corps, an AmeriCorps program.

Talking with Peg before our meeting, it was clear to us that we have a lot to learn from our collective experience in working with Peer Health Educators: what works, what doesn't, and whether this varies from one cultural group to another. This info is invaluable not only to us, but to others who want to develop PHE programs in their communities.

We recognized that this was a wonderful opportunity for self-evaluation through the process of problem identification, looking for root causes, and finding solutions. Collectively, we have the answers, and Peg's role as facilitator is to help us discover these, as well as to contribute to the discussion from her own experience.

What follows is a summary of our discussion from my notes. It is not a verbatim transcript though speakers are identified, so please correct me if I've misinterpreted you or omitted something you think is important.

free mammogram as inducement for women to come to workshops. One concern is that what the PHEs teach is not always accurate.

Our meeting time over, we unanimously agreed to continue this discussion at the next staff meeting July 22, at Asian Human Services, 7th floor, 9:30-12AM, and Peg has graciously agreed to join us again.

Announcements: The day for the year end party to thank ourselves and the PHEs will be **Friday, July 24, 5:30-8PM.** Please put this in your calendars. We decided that it should be Potluck again since we all like trying each other's ethnic foods. The place is yet to be determined. Please let me know if you have any good gift ideas for the PHEs. See ya!

Evaluation Questions:

1. **The PHEs were happy when:**

   a. Teaching others and correcting misinformation;
   b. They like the role of serving others
   c. They like playing a role in preventing cancer
   d. I had a luncheon for them with video tape
   e. I schedule mammograms for their women, and take them for mammograms to the clinic
   f. They are appreciated in various ways
   g. We discuss ways of approaching clients
   h. When I visit them.

2. **The PHEs were unhappy when::**

   a. They can't answer questions about other issues: lose legitimacy, feel inept
   b. Tiiming is difficult...it takes alot of time to teach right.
   c. They didn't like being paid according to the # of contacts/post tests

3. **What I like best about this project:**

   a. Teaching (3)
   b. Helping women be better informed and to know and care about their health.
   c. It concerns every woman, and once a woman comes to us and is trained, she seems motivated and appreciative of our efforts. (At first, they are always skeptical of the whole thing).

4. **What I like least about this project:**

   a. Apathy (2)
   b. Too many forms to fill
   c. Not having my own office on LSD

d. No shows for BSE teaching or post testing
e No shows or calls from PHEs missing meetings
f. Asking people to complete the questionnaires twice
g. Getting hold of the PHEs

5. **What I would like to change:**

a. New PHEs every 6 months (2)
b. Allocate separate money for PHEs
c. Stipend at end of month upon completion of required # of contacts
(I did this and it still didn't work)
d. I would work with 1 or 2 effective PHEs and give them more stipend.

Peg's notes:

Problems:

1.	CHAs discouraged, and feel responsible for failures	
2.	PHEs not motivated	WORK IN TEAMS W/CHA
3.	Mistrust	BUILD TRUST
4.	Dropping out, transience	BUILD IDENTITY
5.	Shyness	BUILD CONFIDENCE
6.	PHEs not really respected	INCREASE LEGITIMACY
7.	Feel inept	ONGOING TRAINING FOR PHEs
8.	Not enough incentive	$$?
9.	Time commitment	
10	Research not understood	

Appendix Project 3

1.) Sample true/false questions

2.) Comments from participants in 1999 classes

APPENDIX

Sample true/false test questions:

Breast Self Exam –
"Women who are postmenopausal don't need to examine their breasts unless they're on estrogen replacement therapy"
"When performing breast examination you need to use enough pressure to cause mild pain"

Symptoms –
"Breast pain is a common symptom of breast cancer"
"Breast lumps that come and go with the menstrual cycle are not signs of breast cancer"

Breast Cancer Facts –
"Breast cancer can be prevented with a low fat diet"
"Breast cancer cannot develop when a woman is breast feeding"

Diagnosis –
"An incisional biopsy only removes a piece of the breast lump for pathological evaluation"
"Breast lumps that can be felt but not seen on a mammogram are benign and require no treatment"

Screening –
"Women over the age of 40 should have a physician breast exam every 3 years"
"A mammogram can detect breast cancer when it is too small to be felt by the most expert physician"

Treatment –
"Mastectomy is the only surgical treatment for breast cancer"
"Once a breast cancer is diagnosed, it should be treated within a week so it doesn't spread"

Risk Factors –
"A woman who has a grandmother who developed breast cancer in her 70's is considered high risk and should be followed more closely than the average woman"
"More than 50% of women who develop breast cancer have a family history of the disease"

Some comments from participants in the 1999 classes:

"Excellent presentation. I've definitely benefited from the classes and I will encourage all my clients to perform BSEs [breast self-exams]."

"Absolutely an excellent teaching program – wholly appreciated useful information."

"Very enjoyable and informative."

"Overall the program was excellent and has been very educational in enhancing my breast exam skills. Thanks."

"I was very impressed with the entire program. I like the idea that with more info on breast self-exams, you are able to perform self-exams comfortably. This was a wonderful educational experience. Keep the good work up!"

Appendices Project 4

Appendix 1

Dolan, NC. Increasing adherence to physicians screening mammography recommendations. The Journal, The Lurie Cancer Center Journal, Summer 1998;7(1):24-29.

Appendix 2

Dolan NC, McDermott MM, Venta L, Morrow M, Martin GJ. Impact of same day screening m availability: Results of a controlled clinical trial. Archives of Internal Medicine, 1999;159:393-398.

Impact of Same-Day Screening Mammography Availability

Results of a Controlled Clinical Trial

Nancy C. Dolan, MD; Mary McGrae McDermott, MD; Monica Morrow, MD; Luz Venta, MD; Gary J. Martin, MD

Background: We conducted a prospective controlled clinical trial in an urban academic general medicine practice to test the effect of same-day mammography availability on adherence to physicians' screening mammography recommendations.

Patients and Methods: Participants were a consecutive sample of 920 female patients aged 50 years or older who had received a physician's recommendation for screening mammography at an office visit and had no active breast symptoms, history of breast cancer, or a mammogram within the previous 12 months. Women were assigned to same-day screening mammography availability (intervention group) or usual screening mammography scheduling (control group).

Main Outcome Measures: Three-, 6-, and 12-month rates of adherence to physicians' recommendations for screening mammography.

Results: Twenty-six percent of women in the intervention group obtained a same-day screening mammogram. At 3 months, 58% of the women in the intervention group underwent the recommended screening mammography compared with 43% of the women in the control group ($P<.001$), increasing to 61% and 49% at 6 months ($P<.001$), and 268 (66%) of 408 vs 287 (56%) of 512 at 12 months ($P = .003$). The difference between the intervention and control groups 3-month adherence rates was most marked among women aged 65 years or older (58% vs 34%; $P<.001$), women who were not employed (54% vs 36%; $P<.001$), and women with a history of having had either no mammograms (39% vs 20%; $P = .02$) or only 1 to 2 mammograms (57% vs 38%; $P<.001$) within the last 5 years.

Conclusions: Same-day mammography availability increased 3-, 6-, and 12-month screening mammography adherence rates in this urban academic general medicine practice. The effect was most marked among women aged 65 years or older, women who were not employed, and those who had had fewer than 3 mammograms in the last 5 years. The efficacy of this intervention in other settings still needs to be demonstrated.

Arch Intern Med. 1999;159:393-398

From the Division of General Internal Medicine (Drs Dolan, McDermott, and Martin), Departments of Preventive Medicine (Dr McDermott), Surgery (Dr Morrow), and Radiology (Dr Venta), Northwestern University Medical School, Chicago, Ill.

SCREENING mammography has been shown to decrease breast cancer mortality in women aged 50 years or older by up to 30%.[1-3] The benefits of breast cancer screening to reduce mortality in the population can be achieved only if screening guidelines are followed and a large proportion of women receive screening examinations regularly. While recent data show that the proportion of women reporting recent mammography has substantially increased from 1989 to 1995, 30% to 40% of women aged 40 years or older report that they have not had a mammogram within the last 2 years.[4-6] Although lack of a physician's recommendation is an important cause of underutilization,[7-12] among women seen in a physician's office who have not had a recent mammogram, adherence rates to a physician's recommendation are only 45% to 60%.[13-15]

In a previous prospective observational study[15] among women aged 50 years or older who received a physician's recommendation for screening mammography, we identified "inconvenience" as one of the most frequently cited reasons for not obtaining the test. Other observational studies[16,17] have also suggested that factors affecting convenience of screening mammography are barriers to adherence.

These data suggest that increasing the convenience of screening mammography may increase screening rates. We hypothesized that providing women with the opportunity to get their screening mammogram immediately after the appointment at which it was recommended (same-day mammography) would improve adherence.

To test the effect of this strategy on screening mammography adherence, we conducted a controlled trial to compare same-day screening mammography availability

PATIENTS AND METHODS

STUDY SITE AND PARTICIPANTS

The study site was an urban academic general internal medicine practice with a hospital mammography center located 3 blocks away. The practice site was staffed during the time of the study by an average of 30 attending physicians and 62 house staff. Approximately 77% of all patients during the study period had an attending physician and 23% had a house staff as their primary care physician. Consecutive female patients aged 50 years or older presenting for new or return visits between February 1, 1995, to September 1, 1996, were eligible for the study. Women were excluded if they were presenting for an acute care visit, had obtained a mammogram in the previous 12 months, had a history of breast cancer, had an active breast symptom at the time of the visit, or had not received a recommendation for a screening mammogram from their physician at the index appointment. Acute care visits were defined as visits scheduled within the previous 24 hours for an acute medical problem such as a cold or back pain. At the study practice, receptionists scheduling the appointments designated the visit type at the time an appointment was made. Having had a mammogram within 12 months was used as an exclusion criterion to capture all women who would be eligible to receive a physician's recommendation for a screening mammogram. The study protocol was reviewed and approved by the Institutional Review Board.

ENROLLMENT

A research assistant asked eligible women to complete a study questionnaire at the time of check-in and attached screening mammography recommendation physician-prompting sheets to the charts of participating patients. Physicians documented whether they recommended a mammogram at the study visit. At the time of checkout, a research assistant documented whether patients planned to get the recommended mammogram, and where they intended to get it. Women were then assigned to the intervention or control group according to whether the fourth digit of their social security number was odd or even. Women with an even number were assigned to the intervention group, women with an odd number the control group.

Although women could have had subsequent visits to their physician after study enrollment, mammography recommendation reminders and same-day mammography intervention were provided *only* at the initial visit.

SAME-DAY MAMMOGRAPHY OPPORTUNITY INTERVENTION

Women in the intervention group were offered the opportunity to obtain the screening mammogram immediately after their appointment. Responses and reasons for refusal were recorded. From February 1, 1995, until September 29, 1995 (phase 1 of trial), women who refused the same-day mammogram were asked if they would have been likely to accept if they had known about the opportunity in advance.

The research assistant notified the mammography center of those accepting the offer and directed these women to the center located 3 blocks away. A free minibus service was available for transport to the mammography center. This service was discontinued September 29, 1995, for reasons not related to the study. Women in the intervention group not accepting the same-day mammogram offer were checked out and directed to schedule the mammogram by telephone as per the usual procedure at the study site. Waiting periods for mammography ranged from 1 to 3 weeks from the time of the scheduling telephone call.

ADVANCE NOTIFICATION MAILINGS: PHASE 2

The purpose of phase 1 of the study (February 1, 1995-September 29, 1995) was to evaluate whether a same-day screening mammography opportunity increases screening mammography adherence rates among women aged 50 years or older in a general medicine practice. Because a substantial proportion of subjects in the intervention arm reported that advanced notification of the same-day opportunity would have increased their likelihood of obtaining a same-day mammogram, we designed a second study (phase 2) to test the additional intervention of advanced notification of the same-day screening mammography opportunity. Because phase 1 provides a reference against which with usual scheduling. Because many women in the intervention arm reported that they would have taken advantage of the opportunity if they had known about it in advance, we designed a second phase of the study to test the effect of advance notification of the same-day opportunity along with same-day screening availability on adherence rates.

RESULTS

Of 2039 women aged 50 years or older presenting to the office for new or return visits, 722 had had a mammogram within the previous 12 months, 119 had a history of breast cancer, 45 had active breast symptoms at the time of the visit, 57 had not received a physician's recommendation, and 176 declined to participate. Nine hundred twenty women were enrolled in the study, 533 in phase 1 (249 intervention and 284 control) and 387 in phase 2 (159 intervention and 228 control). Intervention and control groups demographic characteristics combined for phases 1 and 2 are summarized in **Table 1**. Women in the intervention group were older, less well educated, more likely to have Medicare, and less likely to be employed compared with control group women. The groups were well balanced with respect to family history of breast cancer, history of breast biopsy, and prior use of screening mammography.

SAME-DAY SCREENING MAMMOGRAPHY RATES

During phase 1 of the trial, 67 (27%) of 249 women in the intervention group underwent a same-day screening mammogram. One hundred two (56%) of the 182 intervention women who did not undergo a same-day mammogram during phase 1 of the trial stated that they would have taken advantage of the opportunity if they had known about it earlier. Of the 159 intervention women enrolled during phase 2 of the trial when advance notifi-

phase 2 screening mammography adherence rates can be compared, we elected to report the results of both phases 1 and 2 in a single article.

Phase 2 of the study began October 1, 1995. Two weeks before their scheduled appointments, potential study participants were assigned to the control or intervention group. Potential control group women were sent an informational postcard on screening mammography. The intervention group women were sent the same information as well as notification of the availability of same-day screening mammography if their physician recommended it. When a woman arrived for her appointment, a research assistant asked whether she remembered receiving the postcard and documented this on the questionnaire.

FOLLOW-UP AND OUTCOME MEASURES

The primary outcome measure was the 3-month rate of adherence to physicians' screening mammography recommendations. Three months was chosen to allow women not undergoing same-day mammography adequate time to complete the screening mammogram. To allow for the effects of delayed adherence among both groups, we looked at 6- and 12-month adherence rates as secondary outcome measures. Adherence rate was defined as the percentage of women who had documentation of having had a screening mammogram within the defined period (3, 6, and 12 months) from their physician's recommendation. Adherence was determined for both groups using computerized radiology records at the study institution. If a woman indicated she was going to obtain the mammogram at another mammography center, the specified site was contacted to determine whether the mammogram had been performed.

To determine whether specific patient characteristics were associated with a greater intervention effect, we also analyzed 3-month adherence rates stratified by the following variables: calendar period (phase 1 vs phase 2), age (<65 years vs ≥65 years), education (high school and below vs more than high school), race (white vs African American), employment status (employed vs not employed), and number of mammograms within the last 5 years (<3 vs ≥3). Other outcome measures analyzed were the percentage of women in the intervention group undergoing same-day mammography, and for phase 1 of the trial, the percentage of women in the intervention group who reported they would have accepted the intervention with advanced notification of the opportunity. To measure patient satisfaction with the intervention, a research assistant called women who underwent same-day screening mammography 1 day after the test. Women were asked to rate their satisfaction with the experience on a Likert scale (1, very satisfied; 5, dissatisfied).

STATISTICAL ANALYSIS

χ^2 Tests were used to compare categorical variables and adherence rates between the intervention and control groups. Two-sample *t* tests were used to compare continuous variables between groups. We performed these analyses separately for phases 1 and 2 and combined. Because the characteristics of control group patients in phases 1 and 2, and intervention groups in phases 1 and 2 were similar, only the combined data are shown. Three-month adherence rate ratios and 95% confidence intervals (CIs) were calculated to compare adherence rates among the subgroups of intervention and control individuals. Because the 3-month screening mammography rates were similar between the control groups in phases 1 and 2 and between the intervention groups in phases 1 and 2, we chose to report the combined results for our subset analyses. When the subset analyses were analyzed separately for phase 1 and 2 participants, our findings were similar to those for the combined analyses. All women who were entered during phase 2 of the study were analyzed in the same subgroup, regardless of whether women actually reported receiving the postcard (intention-to-treat).

Using combined data from phases 1 and 2, unadjusted and adjusted logistic regression analyses were performed to evaluate the effect of the intervention alone and the effect of the intervention after controlling for potential confounding variables. Variables with significant baseline differences ($P \leq .05$) between the control and intervention groups were included in the adjusted logistic regression analysis. The independent variables entered into the model were group status (intervention vs control), age, education level, employment status (employed vs not employed), and primary insurance type (Medicare vs other).

cation postcards were sent, 95 (60%) reported receiving the postcards. Among these 95 women, 20 (21%) had a same-day mammogram. Among the 64 women who did not receive the postcard, 17 (27%) accepted the same-day screening mammography opportunity.

Table 2 summarizes the characteristics of phase 1 and 2 women in the intervention group undergoing same-day screening mammography compared with those who did not. Women who took advantage of the same-day screening opportunity had slightly more education than those who did not and tended to be more likely to take public transportation to their appointments, but did not differ significantly with respect to age, race, employment status, and past use of mammography. Among women who underwent same-day mammography, overall satisfaction with the experience was 1.4 ± 1.0 (mean ± SD) on a 5-point scale with 1 being most satisfied.

MAMMOGRAPHY ADHERENCE RATES

Phase 1

Three months after the recommendation was made, 144 (58%) of 279 women in the intervention group had obtained the recommended mammogram compared with 120 (42%) of 284 in the control group ($P < .001$), increasing to 152 (61%) of 249 vs 140 (49%) of 284, respectively, at 6 months ($P = .006$) and 156 (64%) of 242 vs 158 (58%) of 271 at 12 months ($P = .15$).

Phase 2

Three- and 6-month adherence rates for phase 2 participants were identical to those of phase 1. Three months after the recommendation was made, 92 (58%) of 159

Table 1. Baseline Characteristics of Intervention and Control Groups*

Characteristics	Intervention (n = 408)	Control (n = 512)
Mean ± SD age, y†	64 ± 9	60 ± 10
Education, y†§		
<12	20	16
12	43	38
>12	37	46
Race		
White	40	45
African American	40	39
Other	20	16
Primary insurance†		
HMO	28	36
Non-HMO private	20	21
Medicare	36	25
Medicaid	13	14
None	3	4
Marital status, married	29	33
Employed†§	34	42
Mean ± SD, No. of mammograms within last 5 y§	2.4 ± 1.7	2.4 ± 1.7
History of breast biopsy	17	17
Family history of breast cancer	13	12

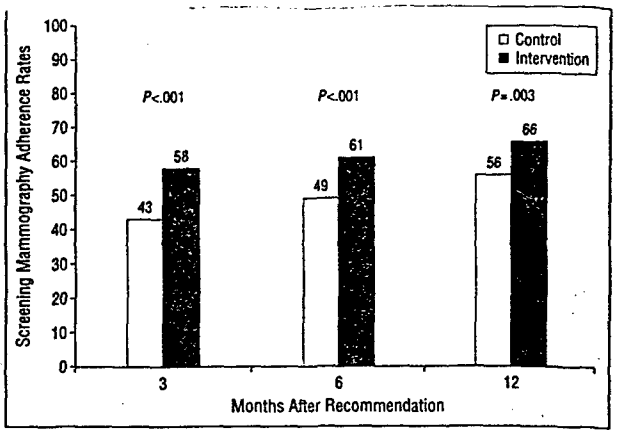
*Values are given in percentages unless otherwise indicated. Intervention indicates same-day screening mammography opportunity; control, usual scheduling; and HMO, health maintenance organization.
†P≤.01 for comparison between groups.
‡P = .03.
§Data were missing on a small number of patients.

Table 2. Comparison Between Women in the Intervention Group Who Underwent Same-Day Screening vs Those Who Did Not

Characteristics	Same-Day Screening Mammogram (n = 104)	No Same-Day Screening Mammogram (n = 304)
Mean ± SD		
Age, y	62.9 ± 8.0	64.0 ± 9.8
Education†	13.1 ± 3.3	12.3 ± 3.6
Race, %		
White	42	39
African American	39	40
Other	19	21
Employed, %	37	33
No. of mammograms within last 5 y, mean ± SD	2.6 ± 1.6	2.5 ± 1.8
Uses public transportation to get to appointments, %‡	48	39

*P = .03.
†P = .09.
‡Data were missing on a small number of patients.

of those in the intervention group had obtained the recommended mammogram compared with 98 (43%) of 228 in the control group (P = .003), increasing to 97 (61%) of 159 vs 111 (49%) of 228, respectively, at 6 months (P = .006) and 106 (67%) of 159 vs 123 (54%) of 227 at 12 months (P = .01). The **Figure** illustrates the overall adherence rates of the intervention and control group women combined for phases 1 and 2 of the trial.



Three-, 6-, and 12-month screening mammography adherence rates among the intervention group (n = 408) (same-day screening mammography availability) and the control group (n = 512) (usual scheduling) women for phases 1 and 2 combined.

SUBSET ANALYSES

The results of the subgroup analyses for combined data from phases 1 and 2 are summarized in **Table 3**. All subsets of women except those who had 3 or more mammograms in the last 5 years benefited from the same-day screening intervention. The difference between the intervention group's and control group's 3-month adherence rates was most marked among women aged 65 years or older (58% vs 34%; P<.001), women who were not employed (54% vs 36%; P<.001), and women with a history of either no mammograms (39% vs 20%; P = .02), or only 1 to 2 mammograms (57% vs 38%; P<.001) within the last 5 years.

In a logistic regression analysis controlling for age, education, race, employment status, and primary insurance type, the odds ratio for the intervention group undergoing mammography was 1.9 (95% CI, 1.7-2.2) at 3 months, 1.7 (95% CI, 1.4-1.9) at 6 months, and 1.5 (95% CI, 1.1-2.1) at 12 months.

COMMENT

The results of this study suggest that the availability of same-day screening mammography increases rates of adherence to physicians' screening mammography recommendations among women aged 50 years or older and is associated with high levels of satisfaction. Our data also suggest that advance notification of this opportunity may not increase its use.

Previously studied patient-directed interventions designed to increase screening mammography rates have included mailed invitations to participate in screening, mailed reminders, mailed booklets based on the Health Belief Model, educational videos, tailored letters, and telephone counseling.[18] With the exception of programs using mobile mammography vans, however, few studies have used access-enhancing interventions.[18]

Although this is the only controlled trial we are aware of that evaluates the effectiveness of same-day screening mammography availability on adherence, previous data suggest that a same-day mammography opportunity may be associated with greater use of mammography.[17] McBride et al,[17] in a study of women in a health care maintenance

Table 3. Rates of Adherence to Physician's Screening Mammography Recommendations According to Group Status and Selected Subgroups*

Subgroups	% Adherence (No. Adhering at 3 mo/ No. in Subgroup)		Adherence Rate Ratios (95% CI)	P
	Intervention (n = 408)	Control (n = 512)		
Phase of trial†				
1	58 (144/249)	42 (120/284)	1.37 (1.15-1.63)	<.001
2	58 (92/159)	43 (98/228)	1.35 (1.10-1.64)	.003
Age, y				
<65	58 (132/229)	46 (172/375)	1.26 (1.07-1.47)	.005
≥65	58 (104/179)	34 (46/137)	1.73 (1.33-2.26)	<.001
Education, y‡				
≤12	54 (130/241)	39 (103/264)	1.38 (1.14-1.67)	<.001
>12	64 (91/142)	49 (110/224)	1.30 (1.08-1.56)	.005
Race				
White	62 (101/163)	47 (108/231)	1.32 (1.10-1.58)	.002
African American	56 (91/163)	41 (84/203)	1.35 (1.09-1.67)	.006
Employment				
Employed	66 (91/139)	52 (113/216)	1.25 (1.05-1.49)	.01
Not employed	54 (145/269)	36 (105/296)	1.52 (1.26-1.84)	<.001
Last mammogram‡				
Within last 1-2 y	67 (132/197)	50 (123/244)	1.35 (1.14-1.60)	<.001
>2 y ago	51 (98/194)	37 (90/245)	1.30 (1.07-1.54)	.004
No. of prior mammograms, last 5 y				
No mammograms	39 (25/61)	20 (14/71)	1.63 (1.04-2.57)	.02
1-2 mammograms	57 (84/147)	38 (77/203)	1.39 (1.15-1.69)	<.001
>3 mammograms	67 (114/171)	59 (118/201)	1.14 (0.97-1.40)	.11

*Intervention group indicates same-day screening mammogram availability; control group, usual scheduling; and CI, confidence interval.
†Phase 1, no mailings; phase 2 intervention women were mailed postcards with general mammography information plus notification of same-day mammography opportunity at their upcoming appointment; control group women were mailed postcards with general mammography information only.
‡Data were missing on a small percentage of patient.

organization, found that nonparticipants in screening mammography had more trouble getting to the facility, had to travel farther, and were more likely to rate the facility as being inconvenient. Margolis et al[16] studied 907 women with scheduled mammography appointments at a public teaching hospital and determined that long waiting intervals for appointments were associated with decreased adherence.

There are several potential explanations for the improved adherence rates observed with same-day screening mammography availability. First, the impact of a physician's recommendation is likely to be strongest at the time it is made. Longer intervals between the time a recommendation is made and the point at which mammography is available may weaken the initial motivation inspired by the physician's recommendation. Second, because same-day screening mammography availability eliminates the need for a separate visit, it saves time, is more efficient, and reduces or eliminates transportation-related problems and costs.

During phase 1 of the trial, 27% of women in the intervention group actually took advantage of the same-day screening mammography opportunity. We found no patient characteristic among women in the intervention group, other than education, associated with acceptance of the same-day screening mammography opportunity. Logistical factors may have contributed to the relatively low rate of acceptance. The mammography center was located 3 blocks from the office site. Inclement weather or difficulty with ambulating may have deterred some women from taking advantage of the opportunity. Another potential explanation is that women were unable to take the time for the mammogram because of other previously scheduled commitments. In fact, a large proportion of intervention group women in phase 1 of the trial indicated that they would have gotten a same-day screening mammogram if they had known about it in advance. To address this second potential barrier, we conducted phase 2 of the trial to test whether use of the same-day opportunity would increase if women knew about it in advance. Our results showed that the percentage of women accepting the opportunity did not increase when women were notified in advance. Many women in phase 2 of the study, when actually faced with that option, were perhaps still not in a state of readiness to comply with the recommendation. Another explanation for the lack of effect of the advanced notification postcards might be that the potential positive effect of the intervention was offset by the discontinuation of the minivan at the same time. Women entered during phase 2 of the study when there was no minivan but who reported not receiving a postcard, however, had the same rate of same-day mammography acceptance as that of intervention women in phase 1. This finding suggests that the discontinuation of the minivan did not have a significant effect on the use of the same-day mammography opportunity, and therefore is not likely to be the explanation for the lack of an effect of the postcards on same-day mammography use.

Our data suggest that women at highest risk for not obtaining a screening mammogram benefited the most from this intervention. Specifically, older age, unemployment, and fewer previous mammograms, factors previously as-

sociated with decreased use of mammography,[7-12,19] were associated with the strongest intervention effects. In contrast, women with frequent previous use of mammography had high rates of adherence regardless of whether they were in the control or intervention group. Therefore, targeting this intervention to those at greatest risk of nonadherence might be an effective strategy for improving adherence while minimizing the potential burden of same-day screening on mammography units.

Several considerations should be taken into account when interpreting these study results. First, the study took place in an urban academic practice with a nearby mammography center. The results may not be generalizable to practices that do not have mammography units in such close proximity. Alternatively, same-day mammography use and subsequent adherence may be even higher among practices that have on-site mammography units. Second, all physicians received a prompt to recommend a screening mammogram to eligible women and only women who received a recommendation were included in the study. Physician prompts are a separate intervention that may have led to overall higher use of mammography in both intervention and control groups. Third, since women who had had a mammogram within the previous 12 months were excluded, the population studied was a relatively select group whose adherence would be expected to be less than that of the entire practice. This is the group, however, in which interventions to improve adherence are most necessary.

A limitation of this study is the unbalanced allocation. Study participants were allocated to the intervention or control group based on whether the fourth digit of their social security number was even or odd, respectively. Digits 4 and 5 of the social security number denote the group number. In general, "even" group numbers (ie, 10, 12, 14, or 16) are assigned consecutively followed by "odd" group numbers (ie, 11, 13, 15, or 17) within a given state or area. Because social security numbers are not randomly assigned, our method of allocation to the intervention vs control group was not random, but instead reflected the social security numbers of patients seen in our general medicine practice. As a result, more women were randomized to the control group, and women allocated to the intervention arm were older, less educated, and more likely to have Medicare insurance compared with the controls. Previous observational data from our institution and others show that increasing age, lower educational status, and Medicare insurance are all associated with lower rates of adherence to screening mammography.[7-12] Therefore, our finding that the same-day mammography intervention resulted in higher rates of screening mammography is especially noteworthy, since the distinguishing characteristics of the intervention group at baseline are known to be associated with lower screening mammography adherence rates. This phenomenon is underscored by our finding that the odds ratio for screening mammography adherence increased after adjusting the bivariate analyses for the observed differences between the intervention and control groups.

In conclusion, same-day mammography availability appears to effectively increase adherence to screening recommendations. This effect is most marked among older women and those who were previously low users of mammography. Targeting women with a history of fewer mammograms for this intervention would be an effective strategy for mammography centers that are unable to accommodate a large mammography-on-demand population. Whether this strategy is effective in combination with other intervention strategies and in other practice settings are areas for future investigation.

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Increasing Adherence to Physicians Screening Mammography Recommendations

Nancy C. Dolan

Available evidence suggests that screening for breast cancer with mammography decreases breast cancer mortality in women age 50 and older.[1-3] Although controversy exists about the best age to begin screening, major professional organizations concur that women 50 years and older should have regular clinical breast exams and screening mammography.[4-5] Despite these recommendations, mammography remains underused.[6-8] While recent data show that the proportion of women reporting recent mammography has substantially increased from 1989 to 1995, up to 40% of women have not had a mammogram within the past two years. [7-10]

Reasons for underuse are complex and involve factors related to women, physicians, and the health care system. Lack of physician referral is one of the most common reasons women cite for not undergoing mammography.[6-7, 11-14] In the Mammography Attitudes and Usage Study 83% of women stated they would undergo mammography if their physicians recommended it.[7] Studies looking specifically at compliance with screening mammography referrals in the outpatient setting, however, have found adherence rates of only 40% to 60%.[15-17] In one cohort of urban black women age 50 and older who were seen in an internal medicine teaching practice, for example, only 70% of women expressed willingness to undergo mammography and of these 60% ultimately obtained the test.[15] Lane and Fine[16] reported an adherence rate of 45% in a group of predominantly white females, both symptomatic and asymptomatic, referred for mammography by Family Practice residents.

While several studies have examined methods for increasing rates of physician recommendation for screening mammography,[18-20] few studies have focused on increasing women's adherence to these recommendations.[21-22] In order to evaluate why women do or do not adhere to physician's recommendations for mammography, Dr. Nancy Dolan, Dr. Douglas Reifler, Dr. Mary McGrae McDermott, and Dr. William McGaghie conducted a prospective observational study in the Division of General Internal Medicine of the Northwestern Medical Faculty Foundation (NMFF).[17] Three hundred forty nine women age 50 and older who received a recommendation for a screening mammogram by a physician or nurse practitioner were followed for three months in order to determine adherence rates and identify clinical predictors of adherence. Overall, 194 (55%) of the women completed mammography screening. Fifteen percent of the women indicated at the time of the recommendation that they did not intend to obtain the mammogram. These women were significantly older than those who agreed to the recommendation were. Figure one illustrates the frequency of reasons for not getting the recommended mammogram, comparing women who refused the test (non-acceptors) to women who intended to get the test but did not (acceptors/nonadherers). Reasons cited for refusal were: belief that mammography was unnecessary (49%), fear of the test (22%), expense (20%) fear of results (12%), inconvenience (12%), and belief that they were too old (10%). Of 298 women who initially

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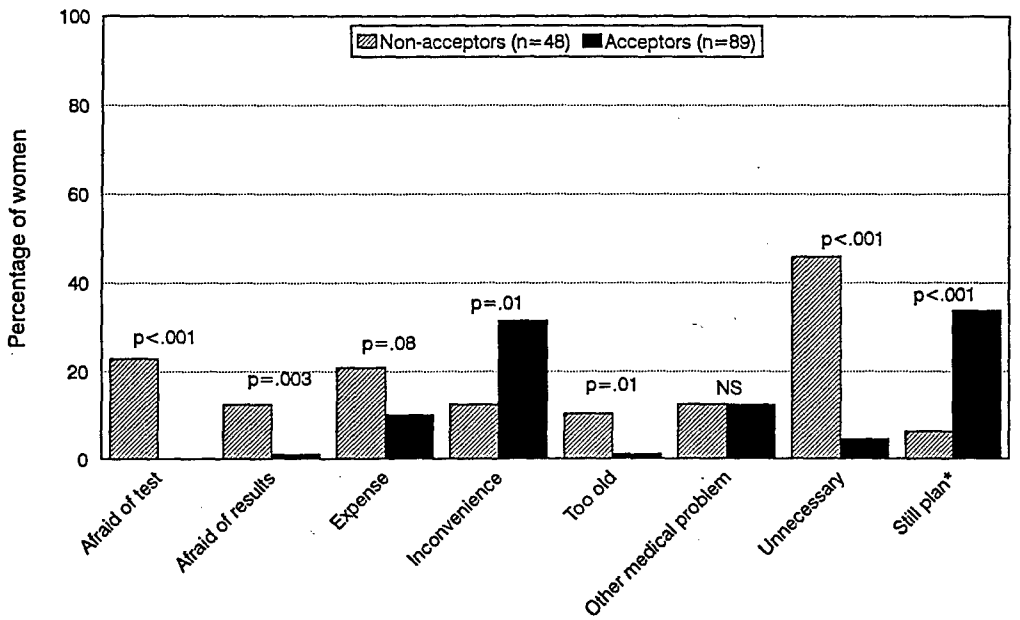
Figure 1.
Comparison of self-reported reasons for not understanding the recommended screening mammogram. Non-acceptors=women who did not accept the recommendation for screening mammography. Acceptors/nonadherers=women who accepted the recommendation but did not obtain the test. Still plan=still plan to get the test in the near future. More than one reason was accepted per person.

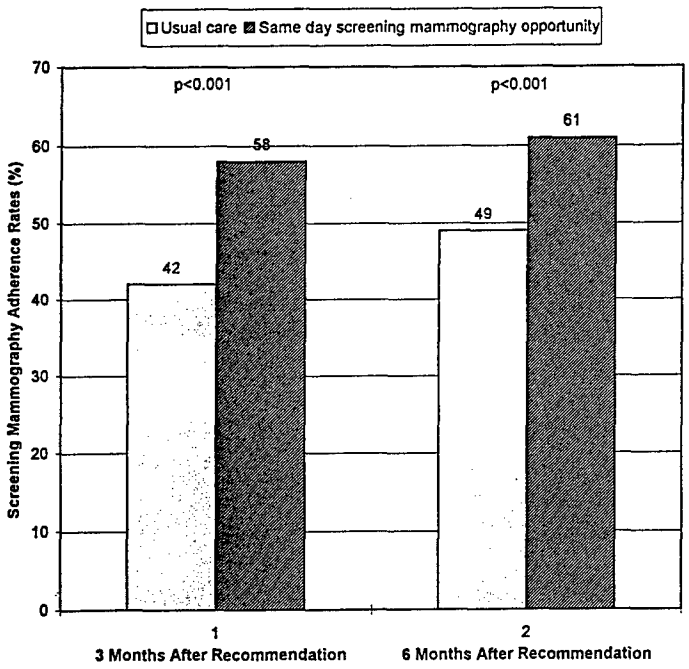


agreed to the recommendation, 63% completed the test within three months. Among women who accepted the recommendation but did not complete the test, the most frequent reason was inconvenience (31%). Not having time, unable to get off of work, and transportation problems were the most commonly cited examples of inconvenience.

This study and others illustrate that adherence to a physician's recommendation for a screening mammogram is at least a two step process including 1) acceptance of the recommendation, and 2) subsequent completion of the test.[15,17] Completion of the test is conditional on whether or not a woman agrees to have the test. It is important to distinguish these two steps as there are unique barriers to adherence at each step and the strategies employed to improve mammography use in these two groups might differ. In the study by Dolan et al. the women who did not accept the recommendation for mammography tended to be older and to think that the test was unnecessary. It was hypothesized that this group may benefit from individualized education in breast cancer screening at the time of the recommendation. Whereas, it was hypothesized that women who agreed to the test but who did not ultimately obtain the mammogram may benefit from reminder systems, more aggressive follow-up, or interventions aimed at increasing the convenience of the test.

To test the hypothesis of whether providing an intervention to increase the convenience of mammography would improve adherence to physician's recommendations, Drs. Dolan and McDermott in collaboration with Dr. Gary Martin, Dr. Monica Morrow, and Dr. Luz Venta completed an intervention trial evaluating the effect of offering same day mammography on adherence rates. In this study women age 50 and older presenting to an urban academic general medicine practice without active

Figure 2.
Three and six month screening mammography adherence rates among the intervention group (same day screening mammography availability) women (n=249) and the control group (usual scheduling) women (n=284)



breast symptoms, history of breast cancer, or a mammogram within 12 months were eligible. After the visit, eligible women who received a physician's recommendation for a screening mammogram were randomized into control and intervention groups. Women in the intervention group were offered the opportunity to receive the mammogram directly after the visit while women in the control received not additional intervention. Satisfaction level among women obtaining the same day mammogram was measured on a five-point scale (1=highly satisfied, 5=dissatisfied). The primary outcome measure was the three month adherence rate i.e. the percentage of women who had obtained the recommended mammogram after three months.

There were 533 women enrolled in the study, 249 in the intervention group and 284 in the control group. Although only 65 (26%) of the women in the intervention group received a same day mammogram, two thirds of the women in the intervention group who did not undergo same day mammography stated they would have if they had known about it earlier. Among women who obtained a same day mammogram, the mean satisfaction level with the experience was 1.2 (SD+/-0.88) and 96% stated they would take advantage of this opportunity again in the future if it was available. The same day mammography availability was associated with significantly higher rates of screening mammography. Three months after the recommendation was made, 58% of those in the intervention group had obtained the mammogram compared to 46% of those in the control group ($p<0.001$) (figure 1). This percentage increased to 61% versus 49% at six months ($p<0.001$).

Although only 26% of the women in the intervention group took advantage of the same day opportunity, a significant proportion of those who did not stated they would have if they had known about it earlier. To test whether notifying women in advance of the same day mammography availability would increase the number of women taking advantage of the opportunity and further increase adherence rates, the protocol to the initial study was modified and a follow-up study was performed. In that study, two weeks prior to their scheduled appointments, potential study participants were assigned to control or intervention groups. Potential control group women were sent an informational postcard on screening mammography, while potential intervention group women were sent the same information as well as notification of the availability of same day screening mammography if their physician recommended it.

TABLE 1.

Rates of Adherence to Physician's Screening Mammography Recommendations According to Group Status and Selected Subgroups

Subgroups	% adherence (No. adhering at 3 mos/No. in subgroup) Intervention* (n=408)	Control* (n=512)	Adherence rate ratios (95% CI)	p-value
Phase of trial†				
Phase I	58(144/249)	42(120/284)	1.37(1.15 to 1.63)	<0.001
Phase II	58(92/159)	43(98/228)	1.35(1.10 to 1.64)	0.003
Age				
Younger than 65	58(132/229)	46(172/375)	1.26(1.07 to 1.47)	0.005
65 years and older	58(104/179)	34(46/137)	1.73(1.33 to 2.26)	<0.001
Education‡				
12 years or less	54(130/241)	39(103/264)	1.38(1.14 to 1.67)	<0.001
More than 12 years	64(91/142)	49(110/224)	1.30(1.08 to 1.56)	0.005
Race				
Caucasian	62(101/163)	47(108/231)	1.32(1.10 to 1.58)	0.002
African American	56(91/163)	41(84/203)	1.35(1.09 to 1.67)	0.006
Employment				
Employed women	66(91/139)	52(113/216)	1.25(1.05 to 1.49)	0.01
Not employed	54(145/269)	36(105/296)	1.52(1.26 to 1.84)	<0.001
Last Mammogram‡				
Within past one to two years	67(132/197)	50(123/244)	1.35(1.14 to 1.60)	<0.001
More than two years ago	51(98/194)	37(90/245)	1.30(1.07 to 1.54)	0.004
Number of prior mammograms‡				
No mammograms in past five years	39(25/61)	20(14/71)	1.63(1.04 to 2.57)	0.02
One to two mammograms in past five years	57(84/147)	38(77/203)	1.39(1.15 to 1.69)	<0.001
Three or more mammograms in past five years	67(114/171)	59(118/201)	1.14(0.97 to 1.40)	0.11

* Intervention group=same day screening mammogram availability; Control group=usual scheduling

† Phase I: no mailings. Phase II: Intervention women were mailed postcards with general mammography information plus notification of same day mammography opportunity at their upcoming appointment; Control group women were mailed postcards with general mammography information only. Adherence rates among those women in the intervention and control groups that reported receiving the postcards were 63% (60/95) and 48% (58/121) respectively.

‡ Data were missing on a small percentage of patients.

The results of the follow-up study were surprising. Despite the high number of intervention women who had previously stated they would have taken advantage of the same day mammography opportunity if they had known about it earlier, rates of completing same day mammography and overall adherence were relatively unaffected by advance notification intervention.

To determine whether specific patient characteristics were associated with a greater same day mammography effect, pooled data from two studies was used to perform selected subgroup analyses. (Table 1) All subsets of women except those who had a history of three or more mammograms in the past benefited from the same day mammography intervention. The difference between the intervention and control group three month adherence rates was most marked among women age 65 and older. (58% vs. 34%, $p<0.001$), women who were not employed (54% vs. 36%, $p<0.001$), and women with a history of fewer than three mammogram within the past five years (54% vs. 34%, $p<0.001$).

Having established that offering same day mammography, with or without advanced notification, is an effective intervention to increase adherence to mammography recommendations, Dr. Dolan and colleagues will next be testing same day in additional practice settings including a geriatrics practice, an urban private practice, and a public health clinic. In addition to evaluating the effectiveness of same day mammography in these settings, they will also be testing the effectiveness of targeted educational messages on adherence rates.

While it is encouraging that there continues to be a strong secular increase in mammography use since the 1987 National Healthy Interview Survey reported that one-third of women had ever had a mammogram, it is now important to focus efforts towards increasing the proportion of women who are receiving regular mammograms and targeting those populations who are lagging behind, particularly older women and those of lower socioeconomic status.

Although women's adherence to physician's recommendations for screening mammography is just one component of mammography utilization, it is a component which must be addressed in order to optimize the frequency with which women take advantage of routine breast cancer screening. It is hoped that with implementation of innovative interventions and educational interventions that have been proven to be effective, we will continue to become closer to this goal.

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Appendices Project 5

Appendix 1

Knight, S. J., Gapstur, S. M., Fitzgibbon, M. L., Losada, A., Blackman, L. R., Hogan, K., DeLa Torre, G., Avellone, M. E. (SBM, 1999). Breast self-examination in Hispanic women: Criterion related validity of a stages of change measure.

BREAST SELF-EXAMINATION IN HISPANIC WOMEN: CRITERION-RELATED VALIDITY OF A STAGES OF CHANGE MEASURE

Sara J. Knight, Ph.D., Susan M. Gapstur, Ph.D., Marian L. Fitzgibbon, Ph.D., Andrea Losado, M.A., Lisa R. Blackman, B.A., Kimberley Hogan, Ed.M., Georgina De La Torre, B.A., Mary E. Avellone, Ph.D.
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Hispanics participate less in breast screening than non-Hispanic whites and blacks. The Transtheoretical Model construct of stages of change has been used to understand breast screening, but little psychometric information is available on its measurement in Hispanics. This study examines the criterion-related validity of a stages of change measure for breast self-examination (BSE) in young Hispanic women. The study is a part of the Mujeres Felices project—an investigation of a nutrition and breast screening intervention for young Hispanic women. One hundred ten Hispanic women aged 20 to 40 completed a breast screening questionnaire and a stages of change BSE measure (SOC-BRE). A nurse rated participant BSE on a proficiency scale. Half of the participants reported behavior on the SOC-BRE indicating contemplation with the rest indicating precontemplation (3.6%), preparation (15.5%), action (3.6%), and maintenance (27.3%). Consistent with SOC-BRE maintenance stage scores, 28.4% reported on the breast screening questionnaire that they had practiced BSE once a month during the last year. SOC-BRE responses correlated significantly with BSE frequency ($r=-0.61$) and BSE knowledge ($r=-0.37$), but were not associated with other screening behaviors or with BSE proficiency. Recency of last mammogram and clinical examination, however, were significantly associated with SOC-BRE scores. These results support the validity of the SOC-BRE for use with young Hispanic women, but point out that practice of early detection is not equivalent to proficient use of these methods. Contact with health providers appears to promote BSE practice.

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Appendix Project 7

Morrow M, Venta LA, Stinson T, et.al. Is core biopsy the diagnostic procedure of choice for all mammographic abnormalities? American Society of Clinical Oncology, Atlanta GA, May 1999.

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Induction Chemotherapy in Operable Breast Cancer: High Pathological Response Rate Induced By Docetaxel. *P. Chollet, P. Bougnoux, S. Amat, S. Charrier, G. Body, I. Van Praagh, R. Chevrier, J. Dauplat and H. Curé. Centre Jean Perrin, Clermont-Ferrand Cedex 1. C.H.U. Bretonneau, Tours, France.*

Docetaxel as single agent obtained a high response rate (46% to 58%) in metastatic breast cancer and was found superior to adriamycin used at the optimal dose of 75 mg/m^2. So it appeared interesting to test this drug in neoadjuvant approach. As of November 1998, 37 patients were included in this multicenticentric phase II trial: 20 are fully evaluable, 17 still under therapy. Between September 1997 and April 1998, these 20 patients of median age 45 years (33–61) received 6 cycles of docetaxel (100 mg/m^2) every 21 days for a total of 15 weeks without hematological growth factor use. Thirteen were premenopausal; clinical TNM staging was 6 stage 2a, 9 stage 2b, 4 stage 3a and 1 stage 3b. Median tumoral diameter was 50 mm (30–90). Pathological proof of biopsy gave 18 invasive ductal and 2 invasive lobular with 1 SBR grade I, 9 grade II and 10 grade III. One out of 20 patients was in progressive disease after 4 cycles; the 19 others underwent surgery after chemotherapy: 15 conservative and 4 modified radical mastectomy. From a total of 118 evaluated cycles, hematological toxicity reached WHO grade 3–4 in 69% of cycles for neutropenia, with 5 febrile aplasia but without anemia and thrombocytopenia. Associated extra-hematological toxicities (WHO grade ≤ 2) were observed in 19 patients and included 11 acute hypersensitivity reactions, 8 cutaneous toxicities and 4 moderate oedema. The tumor responses were evaluated through clinical, ultrasound and mammographic measurements after 2, 4 and 6 cycles of docetaxel.

	Clinical response after			Pathological response after 6 cycles
	2 cycles	4 cycles	6 cycles	
Complete (CR)	1 (5%)	5 (26%)	10 (53%)	5 CR breast and nodes (25%)
Objective	4 (20%)	16 (84%)	16 (84%)	1 *in situ* only (5%)

In conclusion, after 6 cycles, the docetaxel regimen resulted in a high clinical complete response rate of 53% allowing a 75% conservative surgery rate with a high pathological complete response rate of 30%, which could be correlated to a better patient outcome. These results need to be confirmed with a higher number of patients. Updated data will be presented on May 1999 with response evaluation by the three methods (clinical, ultrasound and X ray) and pathological independant review.

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Factors Influencing the Use of Breast Reconstruction (R) Post Mastectomy (M): A National Cancer Data Base Study. *Shirley K. Scott, Monica Morrow, H.R. Menck, D.P. Winchester. Northwestern University, Chicago, IL.*

Many studies have examined factors influencing the use of breast conservation, but little is known about the use of R after M. To determine national patterns of care for the use of R and how they are changing over time we analyzed cases of M done in 1994-5 (n=68,348) and in 1985-90 (n=155,463). In this interval the use of R increased from 3.4% to 8.3% of cases. Variables predicting R were similar in both time periods and are reported for 94-5. Small geographic variations, with the lowest rates of R in the South (6.4%) and highest in the Pacific (12.6%) were noted, while ethnicity, hospital type, and tumor grade did not influence the use of R. The use of R varied with age, with 20% of patients under 40 versus 1.9% over 70 having R. A multivariate analysis of factors significantly influencing the use of R is shown below.

Variable	Odds Ratio	95% CI
Age≤60 vs.>60	7.0	6.7, 7.3
Time 1994-5 vs. 85-90	2.7	2.6, 2.8
Stage 0 vs. other	2.3	2.2, 2.4
Income≥40, 000 vs.<40, 000	2.0	2.0, 2.1

The use of systemic therapy was equal in R and M groups, but radiation was less frequent after R (6.1% vs. 12.4%). Five year survival was 91% ± 0.6 for R versus 85.7% ± 0.2 for M. We conclude that R is not considered a standard option for patients undergoing M, and its use is influenced by both socio-demographic and tumor variables.

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Is Core Biopsy (Cbx) the Diagnostic Procedure of Choice for All Mammographic Abnormalities? *Monica Morrow, Luz Venta, T. Stinson, L. Shih, A. Oquendo, C. Bennett. Northwestern University Medical School, Chicago, Illinois, United States and Chicago VA Health Care System, Chicago, IL.*

Cbx has been advocated for the initial diagnosis of mammographic abnormalities. We prospectively compared the number of surgical procedures to completion of local therapy after Cbx and surgical biopsy (Sbx) on the basis of lesion type, degree of suspicion, and type of local therapy for 1, 852 abnormalities in 1, 550 consecutive patients. The mean age for patients having Sbx was 55.2 years compared to 52.7 for Cbx (p=0.05). Overall, 80.9% of Sbx versus 73.9% of Cbx had a single procedure for diagnosis and/or therapy (p <0.001). There were 409 patients with cancer; 26.1% of Sbx cases and 20.4% of Cbx cases.Those diagnosed with Sbx were more likely to be treated with lumpectomy than those diagnosed with Cbx (71.1% vs. 55.4%; p=.002). Data on surgical procedures in cancer cases is shown.

% Having 1 Surgical Procedure

	Surgical Biopsy	Core Biopsy	p Value
All Cancers	33	84.2	<.0001
Mastectomy	0	88.2	<.0001
Lumpectomy ± Nodes	46.5	84.5	=.001
Lumpectomy Only	73.1	77.8	NS
Presentation			
Calcifications	42.2	89.1	<.0001
Suspicious Calcifications	46.2	90.7	<.0001
Masses	22.4	83.1	<.0001
Suspicious Masses	21.6	84.0	<.0001

The benefit of Cbx in reducing the number of surgical procedures was seen only in patients having mastectomy or axillary surgery. In patients having lumpectomy alone, diagnostic Sbx was as likely as Cbx followed by lumpectomy to be the definitive surgical procedure. Cbx patients in all groups were more likely to require additional surgery after an attempt at 'definitive' local therapy (15.7% vs. 2.1%, p<.0001). We conclude that benefits of Cbx are likely to be marginal in practices with a high proportion of breast conserving surgery as axillary dissection is replaced by sentinel node biopsy.

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Subsequent Sites of Recurrence in Patients with Local, Regional and Soft Tissue Relapse: An Analysis on 1217 Cases. *M. Colleoni, A. O'Neill, RD. Gelber, K. Price, M. Castiglione-Gertsch, AS. Coates, and A. Goldhirsch for the International (Ludwig) Breast Cancer Study Group (IBCSG). Bern, Switzerland.*

Many breast cancer patients with local, regional, and soft-tissue metastases may have a long lasting control of disease, but remain at a very high risk for subsequent relapse. Predicting the sites of relapse may aid the development of treatment strategies to specifically reduce their impact on quality and duration of survival. 6792 patients who entered the randomized clinical trials conducted by the IBCSG between 1978 and 1993 were evaluated. 3714 (55%) experienced relapse (13% had bone and 16% visceral relapse), and of these 1217 (18% of all) had a local, regional or soft-tissue relapse without any other visceral or skeletal metastases as a first event. Within this time frame 404 of the 1217 patients (33%) remained without subsequent event. Subsequent first recurrence was visceral in 28% and bone relapse in 25% of the patients. The incidence of sites of recurrence in younger and older women was similar. The cumulative incidence of bone recurrence at 10-years was 37% and was higher in patients with ER-positive primaries when compared with patients with ER-negative tumors (39% versus 30%). Our data indicate that: 1) local-regional relapse is a frequent event. 2) local-regional relapse predicts a higher risk of subsequent visceral and bone relapse when compared with patients with operable disease. 3) bone relapse is a significant issue especially for patients with ER-positive tumors. Specific treatment to overt bone disease like bisphosphonates might be best investigated in patients with local, regional and soft tissue relapse.

Appendices Project 8

Appendix 1 Abstract submitted for American Society of Hematology Annual Meeting

UTILIZATION OF OUTPATIENT AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT) IS LIMITED BY LACK OF CAREGIVERS. P. Frey,* T. Stinson,* S. Knight,* M. Fishman,* M. Brush,* A. Traynor, L. Gordon, M. Tallman, C. Bennett, J.N. Winter. Division of Hematology/Oncology, Bone Marrow Transplant Program, Department of Medicine and the Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL.

Appendix 2 Abstract Submitted for American Society of Clinical Oncology Annual Meeting

LACK OF APPROPRIATE CAREGIVERS LIMITS UTILIZATION OF OUTPATIENT AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT). P. Frey,* S. Knight,* S. Laub,* T. Stinson,* M. Fishman,* M. Brush,* A. Traynor, L. Gordon, M. Tallman, C. Bennett, J.N. Winter. Division of Hematology/Oncology, Bone Marrow Transplant Program, Department of Medicine and the Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL.

Appendix 1 Abstract submitted for American Society of Hematology Annual Meeting

UTILIZATION OF OUTPATIENT AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT) IS LIMITED BY LACK OF CAREGIVERS. P. Frey,* T. Stinson,* S. Knight,* M. Fishman,* M. Brush,* A. Traynor, L. Gordon, M. Tallman, C. Bennett, J.N. Winter. Division of Hematology/Oncology, Bone Marrow Transplant Program, Department of Medicine and the Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL.

The cost of high-dose therapy with ASCT for the treatment of malignant disease has decreased over recent years and the numbers of patients seeking such therapy nationally has grown exponentially. Improvements in stem cell technologies have made outpatient ASCT practical with family members and friends assuming responsibility for patient care. Currently we are conducting a study to compare medical and non-medical costs and quality of life for outpatient versus inpatient ASCT for a prospective, case-matched cohort of patients. Every new transplant candidate is screened for eligibility and informed about the option of participation in an outpatient program. Ninety six individuals with breast and hematologic malignancies have been screened. Fifty three patients (55.2%) did not have a caregiver or combination of caregivers available. The reasons for caregiver lack of availability included family member responsibility for work, child care, and elder care. Fifteen patients (15.6%) did not have a transplant at this institution because their disease progressed, they elected to go elsewhere for transplant, or they declined transplant. Three patients (3.1%) had medical or psychosocial issues that made them ineligible for outpatient therapy. Insurance issues with eight patients (8.3%) precluded outpatient transplant. Three patients (3.1%) refused outpatient transplant. To date, fourteen patients (14.5%) have proceeded to outpatient stem cell transplant. Despite the potential for cost saving and possible improvement in quality of life, outpatient transplant is applicable to fewer than half of all transplant patients. The impact of the shift in responsibility for caretaking from hospital and insurer to the patients' friends and family that results from outpatient ASCT should not be ignored. The true impact of outpatient transplant on resource utilization and quality of life must be studied in a scientific fashion and will be carefully quantified by this prospective trial.

Appendix 2 Abstract Submitted for American Society of Clinical Oncology Annual Meeting

LACK OF APPROPRIATE CAREGIVERS LIMITS UTILIZATION OF OUTPATIENT AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT). P. Frey,* S. Knight,* S. Laub,* T. Stinson,* M. Fishman,* M. Brush,* A. Traynor, L. Gordon, M. Tallman, C. Bennett, J.N. Winter. Division of Hematology/Oncology, Bone Marrow Transplant Program, Department of Medicine and the Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL.

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DEPARTMENT OF THE ARMY
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